VOLUME 20, ISSUE 13 | JULY 16, 2024

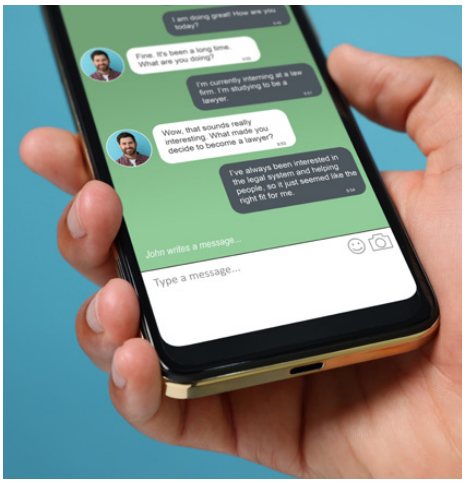
Orthopedics This Week

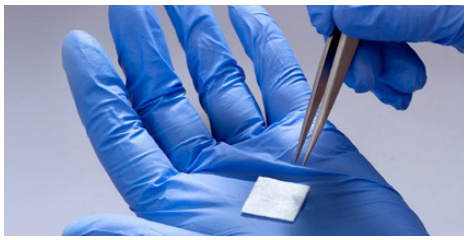
WEEK IN REVIEW

4 One Patient's Amazing Story Pays It Forward – Again and Again >> When Orland Bethel, founder of Hillandale Farms, walked into Dr. Joon Lee's office 10 years ago with severe back pain, he would set off a chain of events that truly exemplifies "giving back."

8 AMA Sends Message to Insurers >> Insurer prior-authorization rules have become one of the largest pain points for both physicians and their patients. The AMA House of Delegates is demanding greater oversight of health insurer use of prior-authorization. Amen.

9 Were Orthofix Execs Terminated for Texts? >> In filings in a California Superior Court, Orthofix's former CEO, CFO and Chief Legal Officer, have given their side of last September's abrupt and unexpected terminations. Here are some of those details.





BREAKING NEWS

For all news that is ortho, read on.

ZIMMER BIOMET | RevelAi HEALTH

CLICK HERE TO DOWNLOAD A PDF VERSION OF THIS WEEK'S NEWSLETTER

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: With mid-year sales and earnings reports coming, the markets in a buying mood largely from softer-than-expected consumer price inflation data last week, as well as a weakening labor market, which makes the odds of a September Fed interest rate cut to around 93%, according to the CME Group's FedWatch tool, although no rate changes are expected at the central bank's meeting later this month in Washington. Trump's assassination attempt also buoyed markets as investors view a 2nd Trump term as one that will be notably business friendly.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Smith & Nephew	14.46%	9.65%	SNN moves up one spot to #1 on the basis of valuation (second lowest Price/Earnings) and a likely 4-5% sales growth report for the first half of 2024.
2	1	Integra LifeSciences	10.98	3.16	The Boston facility is history as the plan now is to move production of PriMatrix and SurgiMend to the state of the art Braintree plant—by 2026—just 10 short miles from the troubled Boston plant.
3	6	Globus Medical	13.71	7.36	It's going to be a good mid-year report for GMED. Yes, courtesy of NUVA, sales will be up 111%, at least, and EPS, consenus on Wall Street, will be around $0.68, up from last year's $0.63.
4	9	Zimmer Biomet	20.78	1.38	It's not likely in the numbers yet, but Tornos and his team are re-energizing Big Blue. Look for 6.40% sales growth for Q2 with a solid EPS gain, possibly to $2.00/share.
5	10	Orthofix	(16.17)	25.06	Massive price appreciation for OFIX. Massimo Califiore has investors delighted with his recent hires. Don't expect much in the numbers yet. Q2 is likely to show a modest 4% sales growth but a positive trend on the bottom line.
6	3	Pacira Biosciences	9.05	(24.13)	This company is too cheap. Blue light special. Particularly with the news that Medicare is RAISING reimbursement 6% for Exparel in the HOPD and ASC settings. Exparel is the only covered single-dose analgesia of its kind for recon and spine.
7	5	Medacta	13.00	(2.72)	This Swiss-based company is one of the fastest growing suppliers of large joint recon systems in the world having essentially doubled in size in the last 5 years to more than $460 million annual sales.
8	8	Bioventus	4.34	(3.39)	Fifth best value in orthopedics, BVS will likely report $138 million in sales for Q2, flat with last year, and about $0.07 EPS. Main thing investors are looking for is stable growth.
9	4	Medtronic	19.17	(4.36)	Both MDT and BVS at #5 in terms of equity pricing and value this week. MDT, which is on a fiscal year, is likely to be reporting flattish earnings at mid-calendar year. Note: cash dividend is now 3.59%.
10	7	ConMed	9.63	(6.45)	Investors sold CNMD off over the last 30 days, but Q2 numbers may bring them back. Sales are likely to rise 8.40% with a very solid EPS gain: $0.91 vs $0.83 last year.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$15.77	$592	25.06%
2	Paragon 28	FNA	$7.58	$629	15.20%
3	SI-BONE, Inc	SIBN	$15.32	$631	14.84%
4	ZimVie	ZIMV	$18.68	$510	12.53%
5	Smith & Nephew	SNN	$28.40	$12,416	9.65%
6	SINTX Technologies	SINT	$5.17	$3	8.61%
7	Globus Medical	GMED	$71.07	$9,598	7.36%
8	Alphatec Holdings	ATEC	$11.25	$1,574	4.36%
9	Aurora Spine	ASG.V	$0.20	$16	4.24%
10	OrthoPediatrics Corp	KIDS	$32.75	$780	4.10%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Dynatronics Corp	DYNT	$0.17	$1	-55.47%
2	Pacira Biosciences	PCRX	$21.76	$1,013	-24.13%
3	ConMed	CNMD	$68.34	$2,105	-6.45%
4	Medtronic	MDT	$77.95	$99,953	-4.36%
5	Xtant Medical Hldgs	XTNT	$0.71	$92	-4.05%
6	MicroPort Scientific	0853	$0.72	$1,325	-3.42%
7	Bioventus	BVS	$6.55	$521	-3.39%
8	Nevro Corp	NVRO	$9.17	$337	-2.96%
9	Medacta	MOVE	$139.49	$2,790	-2.72%
10	Stryker	SYK	$339.37	$129,283	-1.80%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	$21.76	$1,013	17.71
2	Medtronic	MDT	$77.95	$99,953	18.97
3	Johnson & Johnson	JNJ	$149.88	$360,713	19.46
4	ConMed	CNMD	$68.34	$2,105	25.86
5	Zimmer Biomet	ZBH	$108.69	$22,361	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	$0.71	$92	140.14
2	Globus Medical	GMED	$71.07	$9,598	61.92
3	Medacta	MOVE	$139.49	$2,790	54.41
4	Smith & Nephew	SNN	$28.40	$12,416	47.21
5	Stryker	SYK	$339.37	$129,283	35.11

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$28.40	$12,416	-5.90
2	ConMed	CNMD	$68.34	$2,105	1.06
3	Pacira Biosciences	PCRX	$21.76	$1,013	1.83
4	Medacta	MOVE	$139.49	$2,790	1.95
5	Stryker	SYK	$339.37	$129,283	3.16

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Xtant Medical Hldgs	XTNT	$0.71	$92	7.01
2	Integra LifeSciences	IART	$30.01	$2,365	5.54
3	Medtronic	MDT	$77.95	$99,953	4.31
4	Johnson & Johnson	JNJ	$149.88	$360,713	4.09
5	Zimmer Biomet	ZBH	$108.69	$22,361	3.79

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.17	$1	0.02
2	Nevro Corp	NVRO	$9.17	$337	0.79
3	Orthofix	OFIX	$15.77	$592	0.79
4	Aurora Spine	ASG.V	$0.20	$16	0.79
5	Xtant Medical Hldgs	XTNT	$0.71	$92	1.01

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Aclarion	ACON	$0.30	$2	32.53
2	Stryker	SYK	$339.37	$129,283	6.31
3	Globus Medical	GMED	$71.07	$9,598	6.12
4	Medacta	MOVE	$139.49	$2,790	5.46
5	OrthoPediatrics Corp	KIDS	$32.75	$780	5.25

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

One Patient's Amazing Story Pays It Forward – Again and Again

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

When Orland Bethel, founder of Hillandale Farms, walked into Dr. Joon Lee's office 10 years ago with severe back pain, he would set off a chain of events that truly exemplifies "giving back."

Bethel, who runs one of the top five egg producers in the country, had already undergone one procedure for spinal stenosis—but was still in terrible pain.

"Mr. Bethel had been to several surgeons, all of whom proposed that he have a spinal fusion," said Dr. Lee, the clinical director of the Ferguson Laboratory, which focuses on the biology and mechanics of intervertebral disc degeneration. "He was understandably concerned about having rods and screws in his body and so we discussed additional options. We settled on a laminectomy and non-instrumented fusion, which worked out very well for him."

Two years later in 2016 Bethel returned to Dr. Lee and was in even more pain that now encompassed his neck and his arm. "He couldn't raise his arm and had deltoid palsy that turned out to be cervical spinal stenosis and myelopathy. I operated on him immediately and he had a great outcome. We remained connected from 2016 to 2019 during which time we talked about our families and my research."

"He liked the fact that my family immigrated to the U.S. and over time we bonded. We often talked about our early financial struggles, our collective

Anantha Shekhar, M.D., Ph.D., Orland Bethel and Joon Y. Lee, M.D. / Courtesy of Orland Bethel Family Musculoskeletal Research Center-University of Pittsburgh

'grit' to survive and emphasis on education. Initially, he donated several thousand dollars to the department for education and research," said Dr. Lee, now also the Orland Bethel Endowed Professor, University of Pittsburgh School of Medicine (Pitt).

"In 2019 Mr. Bethel established an endowed orthopedic spine research chair, supporting the Ferguson Lab and the legacy of our longtime department chair, Dr. Freddie Fu."

Paying It Forward, Again and Again

"In 2022 Bethel asked me to give some consideration to what type of large project he might fund in the way of a legacy donation," stated Dr. Lee.

"I had always hoped to establish a musculoskeletal research center based on orthopedics, in part because so many talented researchers are siphoned off from academia because they cannot reach the stage of being self-funded."

The Dean of the University of Pittsburgh School of Medicine matched Bethel's $25 million donation and the Orland Bethel Family Musculoskeletal Research Center (BMRC) was born.

"Roughly 90% of those who apply for NIH [National Institutes of Health] funding are rejected," said Dr. Lee to *OTW*. "While research on cancer and Alzheimer's and dementia are more encouraged by the NIH, musculoskeletal (MSK) research is often over-

looked…this despite the fact that 100% of people will suffer from some type of MSK-related pain in their lifetimes."

Now Executive Director of the BMRC, Dr. Lee notes that early to mid-career researchers and clinician scientists face the greatest funding challenges and barriers to generate critical preliminary data. "Without preliminary data to serve as a springboard for larger funding, these researchers are deterred from pursuing promising research and are sometimes forced to undertake 'safe' but uninspiring topics. This is obviously detrimental to innovation and is not how we will move the field forward."

Indeed, says Dr. Lee, approximately 50% of young postdocs leave academia due to a lack of funding.

"Research is a core part of the identity of PittOrtho," said MaCalus V. Hogan, M.D., M.B.A., David Silver Professor and Chair of the Department of Orthopaedic Surgery and Chief of the UPMC Orthopaedic Service Line. "The Orland Bethel Family Musculoskeletal Research Center will position us to drive high impact translational research in a transformative way. We are excited for this future."

Funded and enthused, you might say that Dr. Lee and his colleagues are "putting all of their eggs in one basket." The three-part framework for the new BMRC facility is as follows.

Core Laboratories and Research Groups

The core laboratories and research groups, housed in the Department of Orthopaedics and the Department of Physical Medicine and Rehabilitation, include already existing entities such as the Ferguson Laboratory for Orthopaedic and Spine Research and the Joint Tissue Biology and Engineering Laboratory, for a total of nine groups. The group consists, roughly in equal parts, of basic science research labs and clinical research groups. As they grow, says Dr. Lee, they will also expand into other MSK-related departments within the School of Medicine.

Dr. Lee: "Normally, there is little cross-talk between the basic scientists and clinical research groups…we speak different languages. Those of us on the patient care and outcomes side don't always understand the basic science side of things and conversely, those folks don't see patients, so it's hard for them to understand what we do. Our solution is to make combined meetings obligatory and support researchers with funding. The requirements are that they must incorporate cross collaboration, attend yearly seminars,

and attend monthly meetings on translational research."

New Investigator Program

Much as they are seeking cross collaboration amongst the labs, the Bethel administrators are also putting that in place via new research proposals. "It can be challenging for universities to fund and launch multi-center research studies, but we were convinced that we can elevate the field by expanding knowledge and collaboration across universities. We have partnered with the Orthopaedic Research Society to fund 4-5 Bethel Research Fellows—totaling up to $100,000 annually."

In this, their first year, the program has received over 100 applications from early- to mid-career scientists across the U.S. At this point, they have selected the finalists who will be asked to apply with a full proposal; the winners will be announced this September.

"We are prioritizing those research proposals that have a reasonable chance of obtaining future governmental grants," stated Dr. Lee to *OTW*. "In particular, those deemed 'high risk/high reward' are given additional consideration."

Thinking long term, Dr. Lee notes, "We are hoping that the Bethel Research Fellows will remain in academia and become teachers, mentor graduate students, and encourage *them* apply to become Bethel Fellows."

Education

"I stayed in academia because of the vital interactions with my mentors," stated Dr. Lee. "As such, we will hold yearly seminars and conferences with invited guests. The first one, to be held in 2025, will be known as the Bethel Musculoskeletal Research Retreat. Both invited guest lecturers and Bethel Fellows will come to Pittsburgh to present their work."

Also on the education front, the BMRC offers student stipends to undergraduates, medical students, and Ph.D. candidates. Students will spend two months in one of the core labs, attend weekly lectures and be paired up with a mentor. The first cohort of BMRC student scholars started this summer.

Lastly, to publish and promote the work of the new facility, Dr. Lee and his colleagues are planning a journal: *The BMRC Journal*.

Going Forward

"We have been in discussions with the Bethel family about going further and facilitating a spinoff of the center, namely, a musculoskeletal biobank. The concept is that we would collect tissue and data about the tissues—imaging, demographics, associated diseases, treatment, outcomes, cellular and molecular data. The last of these is known as 'omics' as in DNA (genomics), RNA (transcriptomics), protein, (proteomics), and metabolite (metabolomics). To date, patient evaluation methods have been rather embryonic—patient history, imaging, etc., and we often have difficulty deciding how a patient might fare with one surgical method over another. The biobank will help us narrow things down tremendously, essentially allowing us to take the guesswork out of musculoskeletal care."

"Dr. Freddie Fu truly revolutionized Pitt's department of orthopedics, making it much more academic- and research-oriented. Before him, the department was more practice-oriented and less nationally recognized. The residents he recruited were quite focused on research. Now, thanks to an extremely generous patient, we will be able to continue in this vein. I would like to think that if Dr. Fu was still with us, that he would be extremely excited and proud of this development and our efforts."

In 1956 Orland Bethel borrowed $4,000 from his parents and in-laws and started a business that grew to 10 locations across the U.S. Both now and in the future, Bethel's support will establish a legacy of musculoskeletal scientific discovery, education, and healing.

"He is an extraordinarily unassuming man," says Dr. Lee. "Our team is so thrilled to have his support."

Orland Bethel…a good egg. ♦

AMA Sends Message to Insurers

BY KIM DELMONICO

Insurer prior-authorization rules have become one of the largest pain points for both physicians and their patients.

This recurring issue was tackled at the recently concluded American Medical Association's (AMA) House of Delegates annual meeting in Chicago.

What's required, said the AMA, is greater insurer accountability and transparency, specifically, "greater oversight of health insurers' use of prior authorization controls on patient access to care."

The AMA's House of Delegates is its legislative and policy-making body that includes physicians, residents, and medical students from every state and medical specialty. Delegates work together to form a national physician consensus on current issues.

The AMA will promote greater legal accountability of health insurers in situations where prior authorization hurts patients. This policy is in response to the prior authorization policies of health plans that "conflict with evidence-based clinical practices, jeopardize quality care, and harm patients."

The AMA relied on the knowledge and experience of its policy-making body as well as that of outside sources when developing its policies. Notably it cited physician surveys as well as investigations by the inspector general's office of the Health and Human Services Department and Kaiser Family Foundation. The surveys found that unnecessary authorization controls have led to "serious harm." The investigations "strongly suggest that insurers are denying medically necessary health care."

Source: Shutterstock

AMA Board Member Marilyn Heine, M.D. commented, "Waiting on a health plan to authorize necessary medical treatment is too often a hazard to patient health."

Dr. Heine continued, "To protect patient-centered care, the AMA will work to support legal consequences for insurers that harm patients by imposing obstacles and burdens that interfere with medically necessary care."

The AMA will also remain focused on the information provided by health insurers in prior authorization notifications. Notably, the AMA is prioritizing the need for detailed explanations when access to care is denied.

AMA policy details the information that should be included in the prior authorization denial letters. This includes, per the AMA press release, "a detailed explanation of denial reasoning, access to policies or rules cited as part of the denial, information needed to approve the treatment, and a list of covered alternative treatments." This policy is in response to denial processes by health insurers that are "notoriously opaque, complex, and inconsistent."

Dr. Heine commented, "Health insurer denials must not be a mystery to patients and physicians."

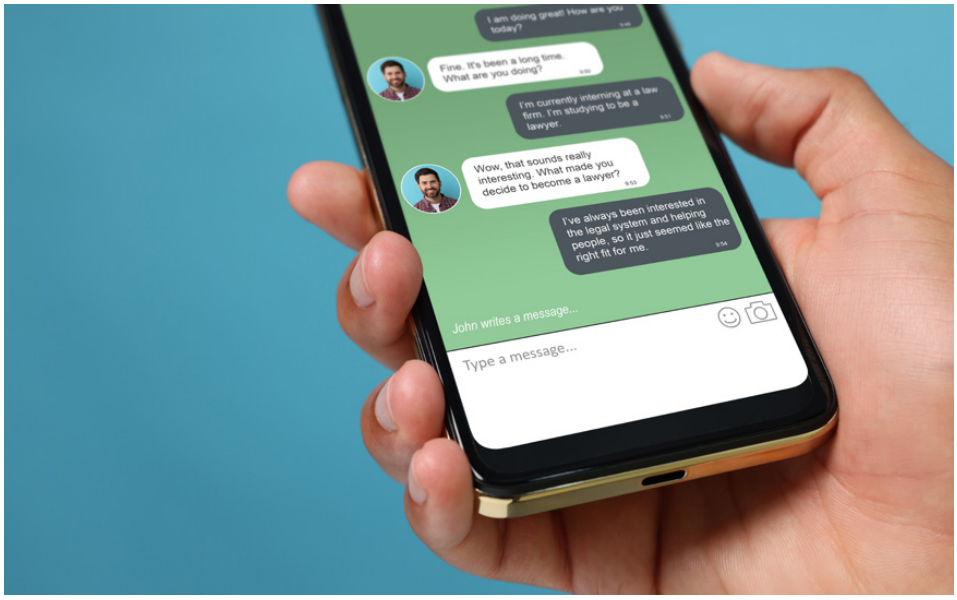
Dr. Heine continued, "Without clear information from an insurer on how a denial was determined, patients and physicians are often left to the frustrating guess work of finding a treatment covered by a health plan, resulting in delayed and disrupted care. Transparency in coverage policies needs to be a core value, an essential principle to help patients and physicians make informed choices in a more efficient health care system." ♦

Were Orthofix Execs Terminated for Texts?

BY KIM DELMONICO

Last year three top Orthofix executives were purportedly fired for "cause." Recent court filings reveal their terminations may have been attributed to texts sent before they were even hired by Orthofix.

OTW recently published an article covering the arbitration filings filed by the ousted executives. For *OTW*'s coverage of the arbitration request filings, see "Ousted Orthofix Execs File Court Challenge."



Source: Shutterstock

What *OTW* didn't cover in the article is the purported "why" behind the firings. Former Orthofix Chief Executive Officer Keith Valentine, former Orthofix Chief Financial Officer John Bostjancic, and former Orthofix Chief Legal Officer Patrick Keran [collectively the "executives"] were terminated from Orthofix on September 11, 2023.

In the Orthofix September 12, 2023, press release announcing the leadership changes, the termination of the executives was purportedly "for cause." In the press release, Orthofix states that its BOD's decision was based on "an investigation conducted by independent outside legal counsel and directed and overseen by the Company's independent directors." From the investigation the BOD allegedly "determined that each of these executives engaged in repeated inappropriate and offensive conduct that violated multiple code of conduct requirements and was inconsistent with the Company's values and culture."

What was allegedly so "inappropriate and offensive" that it necessitated the termination of three executives? According to recent court filings by the executives, it may be a handful of texts sent prior to their employment with Orthofix.

A little background. On January 5, 2023, Orthofix Medical Inc. and SeaSpine Holdings Corporation completed their merger of equals. Around that time the executives took their leadership roles with Orthofix. Sometime in June 2023 the executives purportedly signed their severance agreements which included a dispute resolution agreement. The agreements allegedly covered what would be considered termination "with cause" and "without cause" as well as the severance amounts.

According to Valentine's declaration in his arbitration filings, he claims that "In conjunction with our [the executives] terminations, Orthofix sent us virtually identical written notices of termination. The only 'conduct' identified by the Company as the cause' for our termination were 'business-related text messages' sent privately and solely between me, Bostjancic and Keran that were wholly unrelated to the business and compliance issues that were the subject of the internal investigation."

Valentine continued, "Of the 6,718 text messages collected from our phones, Orthofix identified and provided twenty-four texts exchanges it deemed 'highly offensive'; of those twenty-four, eighteen were written even before I was employed by Orthofix and all but one of which predated my June 19, 2023 Severance Agreement. All of them were exclusively and privately communicated solely between me, Bostjancic and/or Keran. There were no third-party recipients of any of these texts. No recipient objected to their contents or expressed that the texts were unwanted."

OTW will continue to cover this matter as information becomes available. ♦

COMPANY

Orthofix Names New BOD Chair

Michael Finegan, Chair of the Orthofix Board of Directors / Source: Orthofix and Business Wire

Spine and orthopedics company Orthofix Medical Inc. has appointed Orthofix veteran Michael Finegan chair of the Orthofix Board of Directors.

Finegan replaces Catherine Burzik who was re-appointed chair of the Orthofix BOD in June 2023. Burzik had previously served as the chair of the Orthofix BOD from 2021 to 2022.

Orthofix President and CEO Massimo Calafiore expressed gratitude and excitement. Calafiore stated, "We are grateful to former Chair Cathy Burzik for her outstanding leadership, and I would like to thank her for all she has done for Orthofix and wish her the best as she continues to make a difference in the healthcare industry."

Calafiore continued, "We are also excited to welcome Michael as our new Chair. His years of experience in the industry and specifically with Orthofix, will provide the Board with an important dimension and a tremendously valuable perspective to take us into our next chapter of growth."

Finegan is currently the CEO at Acera Surgical, a bioscience company. However, he is no stranger to Orthofix. He has been serving on the Orthofix BOD since December 2023. He also spent

14 years with Orthofix before joining Acera.

Prior to joining Acera, Finegan served in roles of increasing responsibility with Orthofix. Most notably, he served as chief strategy officer for seven years. He also held other positions at Orthofix including President U.S. extremity and SVP business development, president biologics and SVP business development, and vice president corporate development.

Finegan commented, "I have a long history with Orthofix, and it is an honor to be selected to lead the Board of Directors."

Finegan continued, "The company has undergone a transformation and I believe is well-positioned to deliver profitable growth and significant, sustainable shareholder value as we fulfill our mission of providing life-changing solutions for patients." — *KD*

Partnership Creates Largest NE Ortho Platform

Spire Orthopedic Partners' latest partnership announcement has resulted in the largest orthopedic platform in the Northeast.

Spire Orthopedic Partners is an orthopedic and spine care management services organization based in Greenwich, Connecticut. As one of the largest

Spire Orthopedic Partners, one of the nation's largest orthopedic platforms, announces a new partnership with Ortho Rhode Island (Ortho RI) and its affiliated ambulatory surgery center. / Source: Business Wire, Spire Orthopedic Partners, Ortho Rhode Island

orthopedic platforms in the country, it should come as no surprise that its latest partnership with Ortho Rhode Island (Ortho RI) and its affiliated ambulatory surgery center has cumulated in it claiming the title of largest orthopedic platform in the region.

Ortho Rhode Island was established nearly a decade ago and was created from the merger of four Rhode Island orthopedic practices. With its headquarters in Warwick, Rhode Island, Ortho Rhode Island's 35 physicians serve patients from six locations as well as an ambulatory surgery center.

Ortho Rhode Island is dedicated to incorporating leading technologies into its orthopedic care. This includes, according to the company, the use of "robotic assisted surgery, minimally invasive nano operative arthroscopy and orthobiologics treatments." Ortho Rhode Island also provides a range of ancillary services including "advanced imaging, orthopedic urgent care, durable medical equipment, and physical and occupational therapy."

Under the terms of the agreement, Ortho Rhode Island will continue to utilize its current brand. Ortho Rhode Island is led by Michael P. Bradley, M.D., MBA, MS who serves as both president and CEO. Dr. Bradley is also chief of orthopedic surgery at South County Hospital.

As part of the agreement, Dr. Bradley has been named chief medical officer in addition to his current leadership positions. He will continue to lead Ortho Rhode Island and work alongside a newly created clinical governance board.

Dr. Bradley expressed excitement about the partnership, commenting, "At Ortho Rhode Island, our goal is to provide the highest quality clinical outcomes and patient experience."

Dr. Bradley continued, "We are excited to partner with the team at Spire to leverage their capital and management resources to continue to grow Ortho RI in ways that allow us to expand access to our high-quality care in both new and existing markets."

Spire Orthopedic Partners is a majority physician-owned, private equity backed organization. Through partnerships with orthopedic and spine practices, it provides management services. Per the press release, its growing network includes "more than 165 physicians, 1,800 employees, 285 other clinical providers and 40 locations in New York, Connecticut, Rhode Island, and Massachusetts." — *KD*

Zimmer Biomet Partners With Patient Care AI Company

Artificial intelligence (AI) focused RevelAi Health and global medical technology company Zimmer Biomet Holdings, Inc. are partnering together to deliver generative AI orthopedic solutions.

The partnership includes a multi-year co-marketing agreement. The focus of the partnership will be, according to Zimmer Biomet, "to commercialize generative artificial intelligence (AI)-powered engagement solutions." These solutions will be dedicated to "value-based orthopedic care and health equity."

Under the terms of the agreement, Zimmer Biomet will commercialize a number of products and services from the RevelAi Health portfolio. This includes RevelAi Health's patient care-management platform and care team dashboard for providers. Zimmer Biomet will also commercialize any of RevelAi Health's future products or services.

RevelAi Health develops software as a service (SAAS) health technology with an emphasis on generative AI population health solutions. Its solutions have been created with a focus on helping healthcare providers deliver value-based care. Its solutions also help healthcare providers meet many of the requirements of the Centers for Medicare & Medicaid Services (CMS). This includes patient reported outcome measures and social drivers of health screening.

RevelAi Health's portfolio also includes a patient care management system. This system is designed to improve patient engagement and care work-

ZIMMER BIOMET | RevelAi HEALTH

Source: RevelAi Health, Zimmer Biomet Holdings, Inc.

flow. It utilizes both text messaging and a voice agent to enhance patient care. The voice agent is actually guided by a clinician to enhance the patient's experience.

RevelAi Health's CEO Christian Péan M.D., M.S., is an orthopedic trauma surgeon at Duke University School of Medicine. Dr. Péan commented, "Leveraging generative AI to streamline clinical care workflows while addressing socio-demographic disparities is a unique opportunity to drive equitable value-based outcomes."

Dr. Péan continued, "Our AI-enabled asynchronous care model delivers personalized, timely, and effective patient care while reducing clinician burnout. Our collaboration with Zimmer Biomet is a significant step towards ensuring that every patient receives the care they deserve." — *KD*

Partnership Expands Delivery of Silicone Finger Implant

Medical device manufacturer Osteotec and medical device company TriMed, Inc. have come together to expand Osteotec's reach to the United States.

Osteotec is based in the United Kingdom. Its flagship product is the Osteotec Silicone Finger Implant, a one-piece, flexible silicone elastomer implant. The partnership with the Valencia, California-based TriMed will focus mainly on delivering the Osteotec Silicone Finger Implant across the United States.

Osteotec™ | TriMed®

Source: Osteotec and TriMed, Inc.

OTW spoke with Osteotec Associate Marketing Manager Harriet Bawden about what sets this device apart from its competition. Bawden told *OTW*, "Osteotec Silicone Finger offers a highly established surgical option for management of replacement of the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joints of fingers where conservative treatment has failed."

Bawden continued, "Clinical benefits include restoration of function of MCP and PIP joints post-implantation, improvement of range of motion and a reduction of QuickDASH score. In PIP, pain reduction, evidenced by reduction of Pain VAS score."

Bawden added, "The single instrument tray has been designed for ease of use for surgeons and scrub staff, the color-coded rasps are device-specific, and dedicated to a particular size of implant. This enables bone preparation and implant sizing tailored to the patient's anatomy."

Per the press release, the implant is designed to "improve the function" of MCP and PIP joints "disabled by osteoarthritis, rheumatoid arthritis or joint trauma and reduce pain in affected joints." The implant is available in 11 sizes and is currently available in the United States from TriMed.

This is not the first time the companies have worked together. In the press release, Osteotec Sales and Marketing Director Dean Stockwell explained in part, "Osteotec has successfully distributed the TriMed upper extremity portfolio in the UK for more than a decade, and we are proud to build on this long-term partnership to expand access to our products in the United States." — *KD*

Arthrex Innovations: Finalists for 2024 Edison Awards

Arthrex, a company focus on minimally invasive surgical technology, was recently honored with two of its innovations named finalists for the international Edison Awards. Now in its 37th year, the annual awards ceremony recognizes businesses, executives and inventors from around the world who have created innovative products and services that not only solve problems, but also seize opportunities to create new markets. Former recipients include Ted Turner, Elon Musk, and Steve Jobs.

Arthrex was nominated for the SutureLoc™ implant, the first knotless, retensionable soft anchor designed for arthroscopic meniscal root repair. The all-suture soft anchor is designed for retrograde insertion directly under the repair subcortically, improving fixation strength and stiffness by eliminating suture fixation devices in the anterior tibia.

The Product Manager for Knee Arthroscopy, Julia Cuny, told *OTW,* "Meniscus root repair is a technically complicated surgery in the posterior aspect of the knee. Ten to 15 years ago, root repairs were not typically addressed, which can have catastrophic consequences on patients' knees and can lead to rapid cartilage degeneration. The first techniques to market borrowed implants that were designed for other pathologies. These techniques achieve better patient outcomes; however, meniscus root repair still saw high failure rates. Arthrex designed the SutureLoc™ implant to address these failures and to achieve better patient outcomes."

When *OTW* asked how they eliminated the need for a posterior medical portal, Cuny noted, "Due to the large distance between the repair site and fixation, surgeons began using suture anchors for direct tibial fixation. These anchors were pushed into the bone during procedures, requiring posterior portals, which can be difficult and dangerous to patients. To eliminate the use of the posterior portal in repairs, Arthrex focused on achieving joint line fixation by pulling the implant through a transtibial bone tunnel, making the repair more familiar and reproducible to surgeons."

The MIS FiberTak® Achilles SpeedBridge™ repair implant system with Knotless Rip-Stop was also nominated for an award in the Surgical Innovations category. This system provides a minimally invasive approach for inser-

Image 1 The MIS FiberTak® Achilles SpeedBridge™ repair implant system with Knotless Rip-Stop / Image 2: SutureLoc™ implant / Courtesy of Arthrex, Inc.

tional Achilles tendinopathy and allows for a percutaneous approach using a knotless rip-stop and 1.7 mm collagen coated FiberTape in an hourglass pattern of opposition and compression to the bone.

Regarding the MIS FiberTak Achilles SpeedBridge, *OTW* asked Pete Denove, Senior Director of Product Management, Extremities & Trauma, why he thinks such a product hasn't reached the market before now. "Since the launch of the original open SpeedBridge™ technique 13 years ago, minimally invasive surgical approaches have been on the rise. It's a natural evolution that the open procedure moved to more of a minimally invasive technique. The addition of FiberTak® soft anchors increased the suture footprint proximally, creating a stronger repair. This combined with four small incisions (instead of a one large one) makes for a technique that surgeons will rally around to support better patient care."

As for how the hourglass pattern facilitates things, Denove commented, "The hourglass pattern (narrows proximally with the body of the Achilles tendon) mimics the anatomy of the Achilles as it flares or spans out distally. Since the bony prominence is removed proximally and it's important to get solid fixation with the FiberTak anchors and the ripstop, it looks like the narrow part of the hourglass at the top and flares out to get the largest footprint distally, where the SwiveLock® anchors require solid fixation in the distal portion of the calcaneus."

Arthrex previously won three Edison Best New Product gold awards for OrthoPedia, the InternalBrace™ 2.0 ligament augmentation repair system and for Nano arthroscopy along with a bronze award for its Minimally Invasive Bunionectomy procedure. — *EH*

Osteotec and SI-BONE Announce Partnership

Osteotec Limited, a medical device manufacturer and distributor, is now the exclusive distributor of SI-BONE, Inc.'s iFuse Implant System® in the United Kingdom and Ireland.

Osteotec and SI-BONE recently announced the strategic partnership. The agreement went into effect April 1, 2024. Per the press release, it is anticipated that the partnership will "contribute to substantial increases in sales and revenue and accelerate growth." Together, the companies will merge their expertise and technologies to boost marketing opportunities, foster productivity, and drive healthcare outcomes.

SI-BONE Vice President, International Neville Lorimer expressed excitement about the partnership. In the press release, Lorimer stated, "We are excited about working with Osteotec to expand our footprint in the UK and Ireland."

Lorimer continued, "With the assistance of Osteotec's talented commercial team and extensive industry knowledge, we will be able to accelerate our strategic objective of providing superior patient outcomes in these markets."

San Jose, California-based SI-BONE is focused on developing minimally invasive surgical solutions for the sacroiliac joint. Per the press release, the iFuse Implant System is intended for "sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis." The iFuse Implant Systems are "designed to provide immediate stabilization of the SI joint, aiming to enhance the quality of life and offer lasting relief."

OTW spoke with Osteotec Sales and Marketing Director Dean Stockwell about the partnership. Stockwell explained, "We believe this strategic partnership will enhance our ability to reach more surgeons and patients who can benefit from SI-BONE's life-changing treatment. By investing in commercial expansion across the UK and Ireland, we aim to extend the iFuse Implant System's availability and impact."

He continued, "Our shared goals with this partnership are to build on our commercial capabilities to accelerate the growth of the iFuse Implant System across the UK and Ireland and increase its market share. We also want to continue to provide best-in-class educational opportunities for our customers to deepen their understanding of SI joint pain and the benefits of SI-BONE's treatment solutions."

Osteotec is based in Newbury, United Kingdom. For more than 30 years, Osteotec has been a supplier to both private healthcare sectors and the National Health Service. The company has a number of exclusive distribution agreements in the United Kingdom with leading orthopedic companies. — *KD*

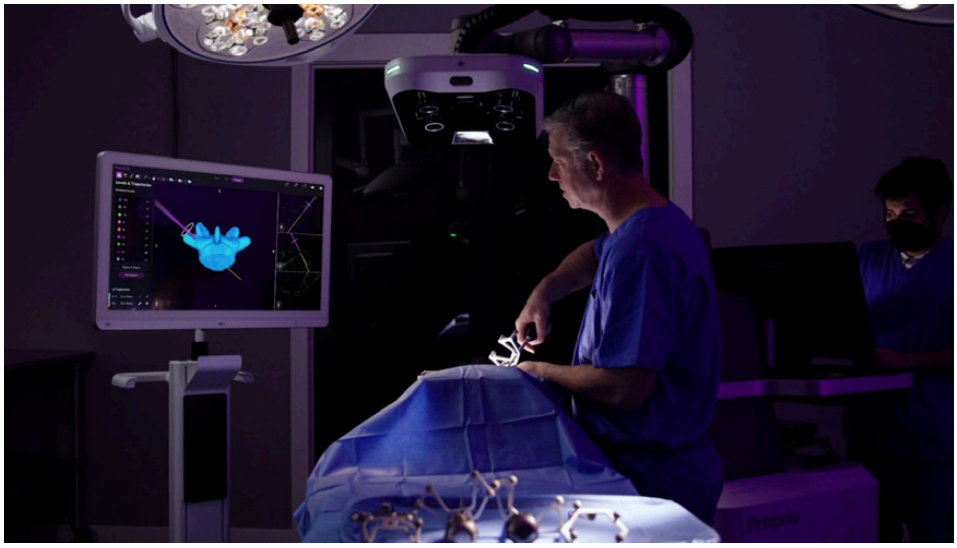
Source: Osteotec and SI-BONE

Robotics Company Proprio Partners with Biedermann Group

An artificial intelligence (AI) surgical technology company (and winner of *OTW*'s 2023 Best Technology in Spine Award) and a venerable, legacy spinal implant supplier have announced a partnership to integrate their respective technologies.

Seattle-based AI computer vision and robotics company Proprio has entered into a partnership with venerable German based Biedermann Group.

Proprio's Paradigm system, which incorporates AI, computer vision, and augmented reality (AR) to provide real-time guidance to surgeons during spine surgery procedures. This system will be integrated with the Biedermann Group's spinal implant technologies.



Propio Paradigm / Source: Propio

Proprio announced the partnership with the German based Biedermann Group earlier this month. *OTW* was able to speak with Proprio CEO and Co-Founder Gabriel Jones about the partnership.

According to Jones, the decision to partner with Biedermann, "Was driven by our shared vision to advance the field of spinal surgery through technology integration. By combining Biedermann's expertise in implant systems

with our AI-driven insights, the partnership aims to significantly enhance surgical accuracy and efficiency. Our collaboration targets the reduction of radiation exposure during procedures, a critical aspect of modern surgical advancements aimed at improving patient safety."

Jones continued, "The partnership is designed to generate valuable intraoperative data, empowering surgeons with enhanced decision-making capabilities based on real-time insights, ultimately leading to improved patient outcomes and an enhanced overall surgical experience."

OTW also spoke with Jones about the respective responsibilities of the partners. Jones explained, "In the initial phase of our partnership with the Biedermann Group, our primary focus is on research, particularly clinical research for adult and pediatric deformity. This phase involves extensive collaboration to lay the groundwork for our joint research efforts. The research component is pivotal as it enables us to delve deeply into the capabilities of surgeons when using the combined technologies of Biedermann's advanced spinal implants and our AI-driven Paradigm system."

Jones added, "We're studying surgeons' ability to align the spine precisely during procedures using these products compared to their usual methods. This analysis is crucial as spine alignment directly impacts surgical success and patient recovery, with misalignment increasing post-operative risks."

Looking forward, this partnership may provide additional benefits for surgeons. Jones hopes that surgeons will "Benefit from a seamless integration of Biedermann's advanced spinal implants with our AI-driven Paradigm system, providing them with unparalleled visualization and guidance during procedures. This integration allows for precise surgical planning and execution, leading to improved accuracy in aligning the spine and reducing the risk of postoperative complications."

Jones continued, "Additionally, the partnership targets the reduction of radiation exposure during procedures, ensuring the safety of both patients and surgical teams. Surgeons will have access to valuable intraoperative data generated by the integrated technologies, empowering them with enhanced decision-making capabilities based on real-time insights, ultimately leading to improved patient outcomes and a higher standard of care." — *KD*

OrthoPediatrics Buys Boston O&P, Closes $80M Debt Financing

OrthoPediatrics Corp. has acquired Boston Orthotics & Prosthetics and closed a debt financing with Mid-Cap Financial.

Massachusetts-based Boston O&P has been dedicated to pediatric orthotics and non-surgical scoliosis treatment options for over 50 years. It currently maintains 26 patient care clinics through its partnerships with medical facilities across the U.S.

Boston O&P's "recent annual historical revenue is approximately $25 million." OrthoPediatrics acquired the company for an upfront cash payment of $22 million. According to the company, "post-closing, OrthoPediatrics cash and restricted cash balance is approximately $60 million."

Prior to the acquisition, OrthoPediatrics entered into a new credit agreement with MidCap Financial providing up to $80 million in capital. This includes a term loan of up to $30 million of capital and a revolving loan providing up to $50 million. OrthoPediatrics drew $10 million from the term loan prior to the acquisition. This new credit agreement replaces a previously unused $50 million line of credit from Squadron Capital.

The acquisition will significantly expand OrthoPediatrics' specialty bracing division. This includes the addition of the Boston Brace, a custom-made scoliosis

Courtesy of OrthoPediatrics and Boston Orthotics & Prosthetics

back brace, and the Boston Band. The Boston Band, per the Boston O&P website, is a "lightweight foam and plastic cranial helmet that treats a number of types of cranial asymmetry."

OrthoPediatrics CEO Dave Bailey commented in part, "We are thrilled to announce the acquisition of Boston O&P, an organization that shares our mission to help children whose lives have been impacted by orthopedic conditions."

Dave Bailey continued, "We are now the first company to have a role supporting the entire continuum of care for pediatric orthopedic patients. This opportunity significantly expands our newly launched OrthoPediatrics Specialty Bracing division and is reflective of the opportunity we saw with pediatric surgical implants at the company's founding." — KD

200% Expansion Completed for Healthcare 3PL Provider

GlobalMed Logistix (GMLx), LLC, a healthcare third party logistics provider has expanded its operational footprint by an additional 200% with the opening of its campus in Norcross, Georgia.

The 65,000 square foot expansion facility completes the 125,000 square foot GMLx Atlanta Campus. The expansion is part of GMLx's growth strategy. The new facility will enable GMLx to add additional medical device manufacturer customers while also enhancing GMLx service capabilities for existing partners. Looking forward, the company will continue to respond to customer needs by adding specialty services.

GMLx President and Chief Operating Officer Scott Vane commented, "At GMLx, we believe in our mantra of 'together we grow' and this expansion

GlobalMed Logistix (GMLx), LLC Company Photo
Source: GlobalMed Logistix (GMLx), LLC

is a testament to the power of that collaboration."

Vane continued, "Over the past year, we've welcomed a remarkable number of team members and supported a record number of customers and transactions. The collective strides we've made have not only strengthened our organization but have positively impacted the customers and patients we serve. As we look to the future, we're excited about this opportunity to continue that growth."

The new facility includes quality control services, tissue distribution services, and cold chain logistics services. The expansion is a medical device grade facility which offers, per the press release, "a dedicated environmental control room to meet the demands of devices with stringent temperature and humidity requirements." There is also a "segregated, 5,700 square foot area dedicated to quality control services which include AQL [Acceptable Quality Limit] inspections, functional testing, and supplier coordination for sterilization."

GMLx Vice President of Sales Hunter Fleetwood stated, "We are proud of our role in the medical device supply chain and that we get the opportunity to help our customers support patients every single day."

Fleetwood continued, "This expansion allows GMLx to continue our focus of providing the best services and service levels in the industry so that our customers can continue to deliver life-changing products to facilities all over the world. Our vision is to positively impact the lives of over one million patients every year and this additional facility is a key factor in helping us achieve that goal." — *KD*

John Rizzo—New EVP at ABANZA

John Rizzo, a seasoned leader with over 30 years in the orthopedic medical device industry, is the new Executive Vice President for U.S. operations at ABANZA, an orthopedics and arthroscopic soft tissue repair company based in Spain.

Prior to joining ABANZA, Rizzo was the senior vice president of sales at Embody Inc., playing a vital role in the company's transformation from pre-revenue to the successful acquisition by Zimmer Biomet in February 2023.

"My 34 years of experience in the orthopedic industry has culminated to this point preparing me for this new role at ABANZA," Rizzo told *OTW.* "Particularly helpful was the period since 2011 when I joined the team at Knee Creations (Subchondroplasty Procedure), overseeing U.S. sales and building from zero to $50M in revenue within six years. During that time, we managed a successful exit with an acquisition by Zimmer in 2013, incorporating subchondroplasty into the Zimmer sales organization; repeating the process in 2015 when Zimmer acquired Biomet."

ABANZA CEO Juan Abascal said, "We are at a critical inflection point as we launch the U.S. commercialization of our best-in-class WASHERCAP™ Soft Tissue Fixation System. WASHERCAP is just the first in a series of planned innovative product releases focused on Soft Tissue repair/fixation."

"We are thrilled to have an executive with John's credentials join the ABANZA family as we take the next steps to building our organization into a Sports

John Rizzo / Courtesy of LinkedIn

Medicine 'Start Up to Watch,' as SmartTRAK® noted earlier this month."

"In early 2020 I joined Embody Inc., running U.S. sales, and building the distribution channel from scratch," said Rizzo to *OTW.*

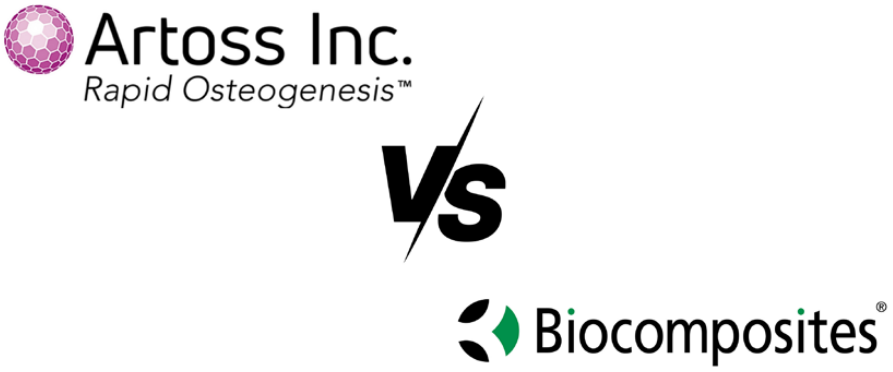
"I was blessed to have found the best combination of sales managers, direct reps, and independent distributors to grow Embody's Tapestry sales consistently month over month and quarter after quarter. This demonstrated growth caught the attention of several potential strategic partners and in the end, Zimmer Biomet acquired Embody in a very successful exit worth up to $275M."

Looking six months out, Rizzo told *OTW*, "We are planning a deliberate and steady approach to commercialization of WASHERCAP in the U.S. during the first 6–12 months."

"Our goal is to work with influential key opinion leaders who can help us build both early clinical evidence and share their experience within their networks. In addition, we will be assembling a team of high caliber independent distributors throughout the U.S. over the coming year. As WASHERCAP has demonstrated an order of magnitude improvement of residual graft displacement vs. any other product on the market we expect rapid adoption." — *EH*

LEGAL

Artoss Wins Synthetic Bone Graft Lawsuit



Source: Artoss Inc., Biocomposites, Vecteezy, and umairashraf

The Federal Third Circuit Court of Appeals has sided with medical device distributor Artoss, Inc. (Artoss) in its dispute with Biocomposites, owner of Artoss GmbH (GmbH), over a bone graft substitute.

The litigation involved NanoBone, an implantable bone graft substitute. Artoss is the North American distributor of NanoBone and Biocomposites GmbH is its manufacturer.

The original lawsuit was filed in 2020 by Artoss, Inc., a U.S. company based in Minnesota. Artoss filed the lawsuit against Artoss GmbH, a company based in Germany, and its owners Thomas Gerber and Walter Gerike. In 2023, U.K.-based medical device company Biocomposites acquired Artoss GmbH.

Artoss sued GmbH for allegedly breaching its distribution agreement with Artoss when it, per the Court of Appeals' Opinion, "refused to ship new NanoBone products to Artoss without advance payment." Artoss then prepaid for inventory and GmbH "unilaterally raised prices on all NanoBone products." GmbH then allegedly terminated the distribution agreement in 2021 claiming that Artoss "registered

certain trademarks on material associated with" NanoBone products.

In 2022, the jury sided with Artoss. The jury found that "GmbH breached the Distribution Agreement and acted wrongfully when it terminated the Agreement" and "Artoss did not breach the Agreement or violate any of GmbH's trademark rights." The jury awarded $1,260,821 to Artoss.

GmbH appealed the decision. On appeal GmbH made four arguments, none of which persuaded the Court of Appeals. In its opinion, the Court of Appeals stated, "The jury had sufficient evidence to conclude that GmbH wrongfully terminated the Distribution Agreement, and none of GmbH's arguments for a new trial or equitable relief is persuasive." The Court of Appeals then affirmed the judgment of the lower court.

According to a press release by Artoss, it is "currently in the process of collecting that judgment, which (with accrued interest) exceeds $1.5 million. "

Artoss CEO Paul Byerley commented in part, "This has been an extremely challenging period in our company's history. I am pleased that the court saw fit to reaffirm our rights under our distribution agreement with Biocomposites GmbH." — *KD*

NJ Ortho Surgeon Pleads Guilty to Opioid Charges

A New Jersey orthopedic surgeon has pleaded guilty to seven counts of illegally prescribing controlled substances to his patients.

Dr. Megariotis could face up to 20 years in prison and a $1 million fine. His sentencing is set for October 15, 2024.

Evangelos Megariotis, M.D. was initially charged with 34 counts of unlawful distribution of controlled substances. This was related to allegations that he dispensed opioid pain medications to five patients, per the indictment, "outside the usual course of professional practice and not for a legitimate medical purpose."

Dr. Megariotis owned and operated Clifton Orthopedic Associates, P.A., an orthopedic surgery practice. He closed his practice on December 31, 2018.

The opioid pain medications listed in the indictment were classified as Schedule II controlled substances and included Oxycodone, OxyContin, and Oxycodone-Acetaminophen. Per the Controlled Substances Act, Schedule II drugs have "a high potential for abuse, with use potentially leading to severe psychological or physical dependence." In 2017, according to the Department of Justice press release, Dr. Megariotis issued prescriptions for the drugs to the five patients from March through November.

The original indictment listed prescription dates between November 2016 and March 2018. It also referenced Schedule IV and Schedule V controlled substances in addition to Schedule II controlled substances. For *OTW*'s coverage of Dr. Megariotis' original indictment, see "Grand Jury Indicts NJ Ortho Surgeon."

The indictment was not the beginning of the allegations against Dr. Megariotis. In 2018, a complaint was filed with the New Jersey State Board of Medical Examiners that contained allegations of professional misconduct and gross negligence. In 2021, the New Jersey Office of the Attorney General and Dr. Megariotis entered into an agreement settling the allegations. As part of the agreement, Dr. Megariotis agreed to retire his license to practice medicine and surgery in New Jersey. He also agreed to return his medical license and Controlled Dangerous Substances registration to the New Jersey State Board of Medical Examiners.

For *OTW*'s coverage of the settlement agreement, see "NJ Ortho Surgeon Admits to Performing Unnecessary Surgeries." — *KD*

Source: Unsplash and Hal Gatewood

510(k) Clearance for Plating System Line Extension

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to a plating system line extension.

According to the 510(k) summary document, the device consists of "titanium plates (straight and T-plate) and locking /non-locking screws (1.3mm) and are offered in a range of configurations to accommodate patient anatomy." Both the plates and screws are non-sterile. The plating system is "intended to bridge or otherwise stabilize bone fragments to facilitate healing."

Tyber Medical LLC submitted the device for clearance. Tyber Medical is an orthopedic device manufacturer based in Bethlehem, Pennsylvania.

Tyber Medical Founder and CEO Jeff Tyber stated, "We expect this product to drive significant growth for our customers."

This clearance expands the range of sizes for the Tyber Medical Mini-Frag System and is indicated for "fixation of fractures, osteotomies, nonunions, malunions, replantations, and fusions of short bones and small fragments of bone including the hand, wrist, foot, and ankle."

The Mini-Frag System is also intended for "reduction and stabilization of non-load bearing long bone fragments." It is not for spinal use.

Tyber Medical Sr. Director of World-Wide Strategic Partnerships Eric Dickson said, "The clearance for the additional plates and screws offers surgeons the ability to treat a larger population, specific to smaller anatomy."

In order to qualify for 510(k) clearance the device must be substantially equivalent to a predicate device. Here, the DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm plates and screws) is listed as the primary predicate device. Two additional predicate devices were listed as Tyber Medical Anatomical Plating System.

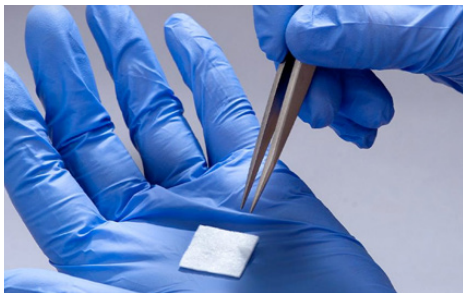
The indications for use of the subject and predicate devices are similar. Additionally, the predicate devices and the subject device have the same technological characteristics. This includes design, material, chemical composition, and principle of operation. — *KD*

Additional Screw and Plate Options, and Indications for Mini-Frag System / Source: Tyber Medical LLC

LARGE JOINTS

Promising Novel Cartilage Implant Data Presented

Clinical data regarding a novel cartilage implant developed in Finland was presented at the 9th Joint Preservation Congress in Warsaw, Poland, June 14-15, 2024.



Askel Healthcare's COPLA® Cartilage implant / Source: Askel Healthcare Ltd

The data represented interim results from a first-in-human pilot clinical trial according to the Finnish manufacturer, Askel Healthcare Ltd. The implant, which is a biodegradable polymer scaffold, is designed to treat symptomatic full-thickness chondral and osteochondral lesions in the knee joint.

Twenty patients are being enrolled in the pilot study. Each patient is asked to make seven visits to the investigational site, participate in a pre-operative baseline screening protocol and then if accepted into the study, be treated with the novel scaffold and bone marrow stimulation. Finally, the study team will be collecting follow-up data from each patient 3 months, 12 months and 24 months.

The implant's brand name is COPLA®.

According to the study's principal investigator, the interim results were very promising.

"As this was the first-in-human trial, there were somewhat conservative expectations on the results. It was great to see and hear how well and how quickly the patients' well-being was improving after the surgery," said Teemu Paatela, M.D., chief orthopedic surgeon and director of Musculoskeletal Businesses at Terveystalo, Finland's largest private hospital chain and the coordinating principal investigator of the pilot trial.

"Clinically significant results were achieved already at 6-week (pain, Visual Analog Scale /Numeric Pain Rating Scale) and 3-month (Knee Injury and Osteoarthritis Outcome Score total and sub scores) follow-up timepoints and the improvement continued at 6-months."

"I am very impressed with the initial results of COPLA," commented Kondrad Slynarski, M.D., Ph.D., the coordinating principal investigator of the pivotal trial. "I was very excited to start the pivotal trial and see how my active patients in Poland will benefit from the treatment. I have high hopes for COPLA to deliver similar or even better results as in the pilot trial also within a bigger patient population in the pivotal trial."

"Cartilage defects are prevalent, particularly among athletes, and existing treatments are often unreliable. The initial results with COPLA are impressive, showing promise for active patients by enabling early weight-bearing, swift rehabilitation, and a quick return to activities. However, it is important to note that these outcomes are based on a very small patient sample," Dr. Paatela is also a member of Askel's Clinical Advisory Board.

According to the company, tailoring and placing the implant to the lesion added on average 15 minutes to the length of surgery. No special instrumentation was needed. The first 10 subjects reported significant improvements in knee function and pain levels at the 6-month follow-up point.

In addition, the company reported, the first group of patients required no pain medication at 6 weeks post-surgery. The researchers also found that patients had improved knee movement and strength returning to pre-surgery levels within 3 months.

All patients returned to their pre-injury activity levels between 6 weeks and 3 months, which was maintained at 6 months. Patients reported high satisfaction with the surgery, noting an overall improvement in their quality of life.

When *OTW* asked how they are preparing for the next trial, Petra Raatikka,

Askel's Chief Clinical Officer noted, "The Pivotal Trial will aim to demonstrate the clinical benefits of COPLA in a randomized trial that is designed to show superiority over current surgical standard treatments and will serve as a cornerstone for market authorizations in the U.S. and EU."

"The Askel team is engaging best-in-class vendors with breadth of domain expertise and experience in supporting innovative medical technologies to navigate the clinical trial process. The selected team has successfully worked on numerous medical technologies as an extension to the manufacturer's team to navigate the approval process."

"In addition, all pilot trial data that is coming in is reviewed and pivotal trial planning is adjusted if needed. Askel's strategy involves collaboration with globally renowned orthopedic surgeons and sports medicine specialists in its clinical development. The company has established a prestigious Clinical Advisory Board comprising internationally recognized experts in cartilage damage treatment and they are closely involved with the pivotal trial planning."

According to the company, the scientific article will be published once all 20 patients complete the 24-month follow-up period. — *EH*

HSS: Navigation, Robotics Don't Increase PJI After THA

Given that using computer navigation or robotic assistance during primary total hip arthroplasty (THA) adds operative time and requires more surgical equipment and personnel, what is its impact on periprosthetic joint infection (PJI) after primary THA?

That is the question a team from Hospital for Special Surgery (HSS) in New York asked, leading to their study: "Robotics and Navigation Do Not Affect the Risk of Periprosthetic Joint Infection Following Primary Total Hip Arthroplasty: A Propensity Score-Matched Cohort Analysis," appears in the April 3, 2024 edition of *The Journal of Bone and Joint Surgery.*

Co-author Alberto Carli, M.D. told *OTW*, "We conducted this study in response to the increasing popularity of utilizing robotic assistance for total hip and total knee replacement procedures. Although robotic assistance has been heralded as helping orthopedic surgeons achieve much more precise implant position when performing hip and knee replacement surgeries, the procedure itself takes more time and a large robotic tower with an attached arm must enter the sterile field."

"The arm itself actually enters the surgical wound at times as well," added Dr. Carli. "This then led to the question of whether utilizing robotic assistance leads to increased risk of periprosthetic joint infection (PJI), a rare but devastating complication that can occur after replacement surgery. We therefore undertook this carefully designed retrospective analysis to answer this question."

The team looked at 12,726 patients who had undergone primary THA at their institution between 2018 and 2021, stratifying patients by technique (conventional THA, computer-navigated THA, or robotic-assisted THA and matching them 1:1.

In the THA versus robotic-assisted THA analysis there were 4,006 patients (2,003 in each group). In the THA versus computer-navigated THA group there were 5,288 patients (2,644 in each group).

Computer-navigated-THA and robotic-assisted-THA were associated with longer operative times compared with conventional THA by 3 and 11 minutes, respectively. The rates of PJI after conventional THA (0.2% to 0.4%) were similar to those after computer-navigated THA (0.4%) and robotic-assisted-THA (0.4%).

"We found that, fortunately, use of robotic assistance was not associated with an increased risk of PJI in our matched patient cohorts," stated Dr. Carli to *OTW.* "This is despite all finding that robotic procedures do take significantly longer than procedures with conventional instrumentation. We were not surprised our year-over-year institutional infection rates have barely changed over the last five to six years (despite the increasing use of robotics), but I will say that we were relieved!"

"Although our study involved thousands of patients, given the inherently low infection rates that we achieve after hip and knee replacement, we are still

Source: Shutterstock

statistically underpowered to detect smaller differences in infection rates. That is perhaps the greatest limitation in our paper. This is despite our institution performing the highest volume of hip and knee replacements in North America. Our future efforts will likely involve repeating such an analysis in several years once we have a larger case volume in order to increase our statistical power." — *EH*

SPINE

Study: It All Comes Down to Bedside Manner?

Negative online reviews of individual spine surgeons. Not only not helpful, but misleading.

A team from the Department of Orthopaedic Surgery at the University of Pittsburgh Medical Center set out to assess negative reviews of spine surgeons in the U.S., comparing surgical versus nonsurgical reviewers. Their work, "Characterizing Negative Online Reviews of Spine Surgeons," appears in the June 1, 2024, edition of *Spine*.

"Many of us physicians share the frustration that we are reviewed unfairly online," said co-author Joon Y. Lee, M.D., the Orland Bethel Endowed Professor at the University of Pittsburgh School of Medicine, to *OTW.*

"Unlike typical businesses, physicians as individuals cannot reasonably defend some very negative and ***personal*** online comments. Due to the sensitivity of our interactions with the patients, it is often difficult to rebut or describe in detail the nature of the patient interaction that led to the negative review."

"We wanted to quantitatively and qualitatively analyze the reasons for negative online reviews for spine surgeons to the best of our ability. We wanted to understand the nature of interactions and reasons that would typically lead to the comments."

After acquiring a list of fellowship-trained orthopedic spine surgeons from the American Academy of Orthopaedic Surgeons website., the researchers evaluated 16,695 online reviews, including 1,690 one-star reviews (10.1%). Of this group, 64.7% were written by nonsurgical patients and 35.3% by surgical patients. Nonclinical and clinical comments constituted 54.9% and 45.1% of reviews, respectively.

Surgeons in the South had more "bedside manner" comments (43.3%), while Northeast surgeons had more "poor surgical outcome" remarks compared with all other geographic regions (14.4%). Practicing in the South and Northeast were independent predictors of having complaints about "bedside manner" and "poor surgical outcome," respectively.

"The most interesting result is that the *non-surgical* interactions were the most common reason for negative reviews. Most common category of complaint was for the 'bedside manner' of the surgeon."

"Many uncontrollable factors by the individual surgeons (i.e., how the office staff treated the patient, wait time due to over booking, etc.) were also part of the reasons for negative reviews. Negative reviews due to surgical complications were much less than non-surgical issues. We did not explore this specifically in our article, but the positive reviews tended to be for *surgical* results."

When *OTW* asked what might interfere with surgeons having a better bedside manner, Dr. Lee responded, "I think the reasons vary. It can be both patient and surgeon factors involved. We all have experienced increasing workload within our respective specialty. For surgeons, we work in an incredibly stressful environment in and out of the OR."

"I think that we all have the tendency to trivialize *non-surgical* issues that our patients may experience, which can lead to the perception that the surgeon has a bad bedside manner (ignoring issues, etc.). Also, the studies will not reveal patient related factors, such as personality conflicts between patients and surgeons, difficult/overly demanding patients, etc. Afterall, surgeons are also human, and sometimes we are held to higher standards of patience."

"This study allows us to reflect on how we can modify our interactions with our patients, particularly around non-surgical issues. An interesting relationship we should explore is the correlation between reasons/frequencies of negative reviews and rate of malpractice litigation for a given practice. Difficult but a relevant topic/study." — *EH*

"I'm happy to see you, too."

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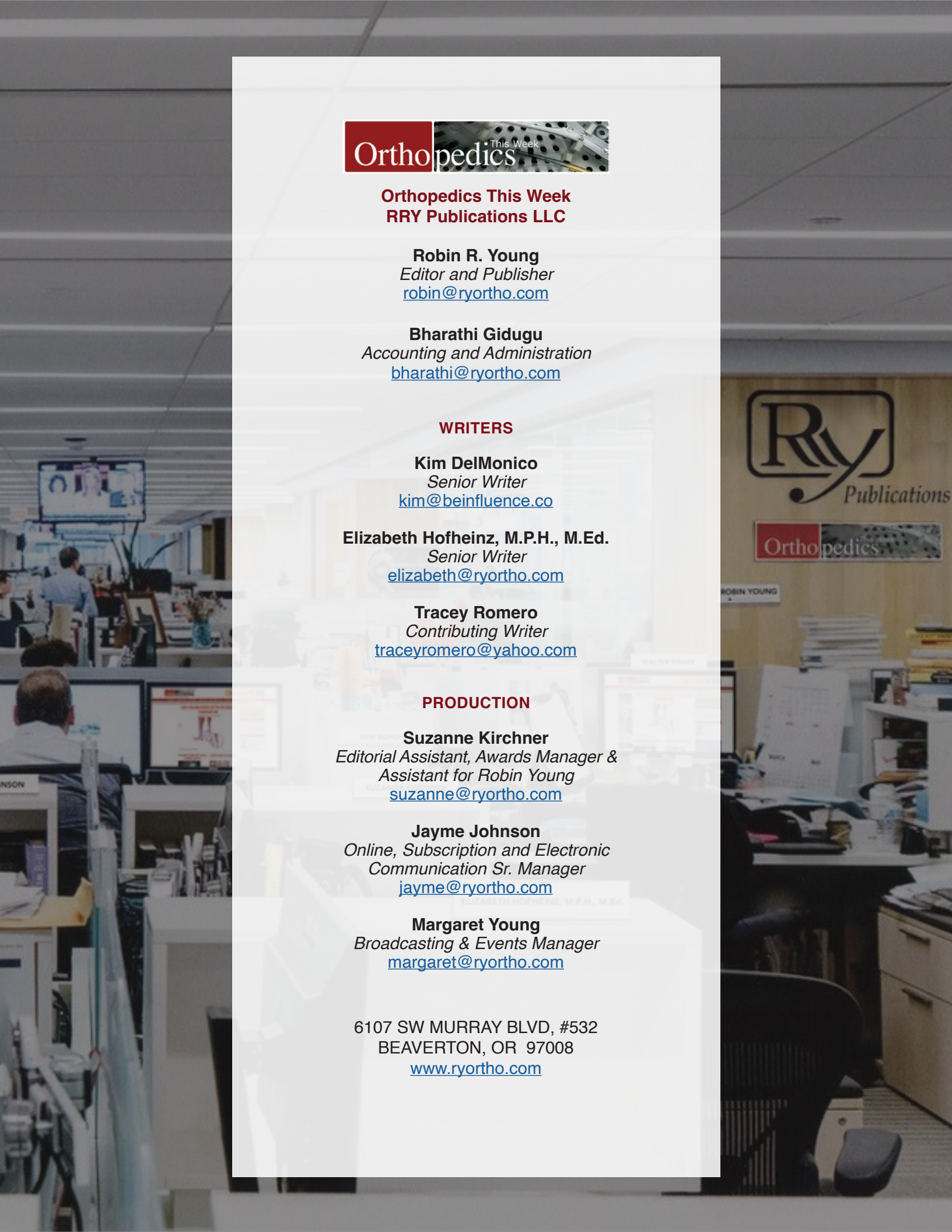

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