

Orthopedics This Week

WEEK IN REVIEW

4 Medicare Adds 4 Key Ortho Interventions to ASC Covered List >> The Centers for Medicare & Medicaid Services (CMS) will now pay for total shoulder arthroplasty, total ankle replacement, hip tendon incision and meniscal knee replacement in both the ambulatory surgery center (ASC) and inpatient settings.

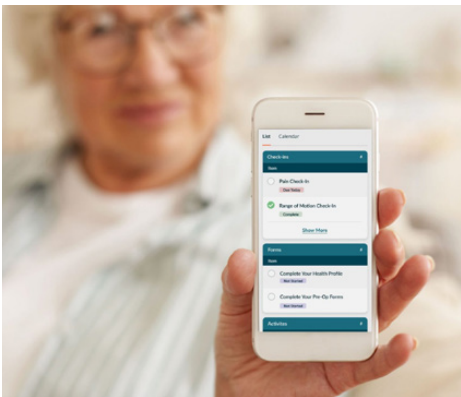
5 Former NUVA and LimaCorporate Exec Takes Top Job at OFIX >> Massimo Calafiore, the former chief commercial officer for NuVasive, Inc., and the current CEO of Villanova, San Daniele del Friuli, Italy-based LimaCorporate has accepted the top job at Lewisville, Texas-based Orthofix Medical Inc.

8 Remote Patient Monitoring Wins AAHKS's 2023 Innovation Award >> Remote patient monitoring, one of the great promises of the digital revolution in medicine, was chosen from a field of 16 submissions to win the prestigious AAHKS Industry Innovation Award.



BREAKING NEWS

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For all news that is ortho, read on.

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: Orthopedic equities appear to be on track to end 2023 in positive territory. Ortho and Spine stocks up 4.7% in 30-days, on average. Power Ranking stocks up significantly more. For Ortho companies, procedure volumes are healthy and two key trends are attracting investors—digital technologies and the structural shift to more surgery in the ASC setting. Here, then, are the 10 most attractive public Orthopedic or Spine companies as measured by PE, PSR or PEG and prospects.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Bioventus	(5.33%)	32.28%	BVS signs deal with Aetna Medicare Advantage to distribute HA injections to their 3 million covered patients. For Q4 most analysts expect BVS to return to profitability.
2	2	ZimVie	(5.96)	38.32	ZIMV attracting buying interest. Low valuation is part of that. Wall Street thinks ZIMV will have the highest future earnings growth rate of all Ortho companies. Admittedly from a low base.
3	6	Integra LifeSciences	17.32	10.20	Integra is restarting its Boston Facility—which closed earlier in 2023 and took \$100 million of IART's most profitable product lines off the market. How much can they get back? Analysts think 50+%.
4	3	ConMed	7.42	9.02	CNMD announces its year-end quarterly dividend. \$0.20 cash per share. 0.73%. Also president sold a few shares. For the final quarter of the year, Wall Street expects 32% sales growth YOY.
5	7	Zimmer Biomet	19.31	11.86	Nice move by ZBH. Ivan Tornos and his management team are making the investment rounds, communicating change, new possibilities and vigor.
6	5	Anika Therapeutics	(20.94)	8.29	Anika, as we wrote recently, is the most interesting company in Ortho right now and appears to be upending three major MSK categories with novel new product launches.
7	9	Axogen	(9.75)	39.07	Massive one-month move my AXOGEN. Senior management made some key executive changes, swapping out one CFO for another.
8	4	Smith & Nephew	10.06	7.35	Smith & Nephew buys CartiHeal for \$180 million—which BioVentus had agreed to purchase roughly 2 years ago, but got cold feet and pulled out. CartiHeal is a sports medicine treatment for cartilage regeneration.
9	NR	Medtronic	19.26	10.65	Medtronic continues its commitment to advanced digital technologies with the announcement to partner with AI-driven innovator Cosmo Intelligent Medical Devices.
10	8	Pacira Biosciences	12.86	(6.22)	Investors just don't get excited about Pacira. It is now THE #1 cheapest equity in all of Orthopedics and Spine. With one of the highest operating profit margins—12.86%!

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	AxoGen	AXGN	\$7.51	\$323	39.07%
2	ZimVie	ZIMV	\$11.19	\$297	38.32%
3	Bioventus	BVS	\$5.04	\$397	32.28%
4	Nevro Corp	NVRO	\$19.95	\$722	23.15%
5	Alphatec Holdings	ATEC	\$12.71	\$1,732	20.25%
6	Dynatronics Corp	DYNT	\$0.58	\$3	17.11%
7	SINTX Technologies	SINT	\$0.42	\$2	15.54%
8	SI-BONE, Inc	SIBN	\$19.34	\$783	14.37%
9	OrthoPediatrics Corp	KIDS	\$30.53	\$713	12.70%
10	Zimmer Biomet	ZBH	\$117.30	\$24,513	11.86%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MicroPort Scientific	O853	\$1.03	\$1,884	-40.99%
2	Pacira Biosciences	PCRX	\$28.06	\$1,303	-6.22%
3	Orthofix	OFIX	\$11.76	\$432	-0.84%
4	Globus Medical	GMED	\$46.51	\$6,539	1.40%
5	Medacta	MOVE	\$130.12	\$2,602	1.93%
6	Johnson & Johnson	JNJ	\$154.42	\$371,732	2.71%
7	Xtant Medical Hldgs	XTNT	\$1.27	\$165	4.96%
8	Stryker	SYK	\$289.10	\$109,828	5.21%
9	Smith & Nephew	SNN	\$26.28	\$11,476	7.35%
10	Aurora Spine	ASG.V	\$0.31	\$22	7.95%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Integra LifeSciences	IART	\$41.27	\$3,226	17.87
2	Johnson & Johnson	JNJ	\$154.42	\$371,732	18.64
3	Medtronic	MDT	\$79.35	\$105,508	18.83
4	Globus Medical	GMED	\$46.51	\$6,539	23.89
5	Zimmer Biomet	ZBH	\$117.30	\$24,513	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Smith & Nephew	SNN	\$26.28	\$11,476	51.46
2	Medacta	MOVE	\$130.12	\$2,602	49.75
3	ConMed	CNMD	\$109.37	\$3,363	40.59
4	Pacira Biosciences	PCRX	\$28.06	\$1,303	35.84
5	Stryker	SYK	\$289.10	\$109,828	32.75

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	\$26.28	\$11,476	-6.43
2	ConMed	CNMD	\$109.37	\$3,363	1.42
3	Globus Medical	GMED	\$46.51	\$6,539	1.47
4	Medacta	MOVE	\$130.12	\$2,602	1.78
5	Stryker	SYK	\$289.10	\$109,828	3.09

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Medtronic	MDT	\$79.35	\$105,508	5.59
2	Integra LifeSciences	IART	\$41.27	\$3,226	4.96
3	Zimmer Biomet	ZBH	\$117.30	\$24,513	3.78
4	Johnson & Johnson	JNJ	\$154.42	\$371,732	3.58
5	Pacira Biosciences	PCRX	\$28.06	\$1,303	3.12

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	\$0.58	\$3	0.06
2	ZimVie	ZIMV	\$11.19	\$297	0.32
3	Bioventus	BVS	\$5.04	\$397	0.78
4	Orthofix	OFIX	\$11.76	\$432	0.94
5	Aurora Spine	ASG.V	\$0.31	\$22	1.13

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SI-BONE, Inc	SIBN	\$19.34	\$783	7.36
2	Globus Medical	GMED	\$46.51	\$6,539	6.39
3	Medacta	MOVE	\$130.12	\$2,602	5.95
4	Stryker	SYK	\$289.10	\$109,828	5.95
5	OrthoPediatrics Corp	KIDS	\$30.53	\$713	5.83

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

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Robin Young | robin@ryortho.com



Medicare Adds 4 Key Ortho Interventions to ASC Covered List

BY KIM DELMONICO

The Centers for Medicare & Medicaid Services (CMS) will now pay for total shoulder arthroplasty, total ankle replacement, hip tendon incision and meniscal knee replacement in both the ambulatory surgery center (ASC) and inpatient settings.

In its 2024 final payment rule for ambulatory surgery centers and hospital outpatient departments (HOPD), CMS added 37 new procedures to its covered procedures list.

These included 26 dental codes and 11 surgical codes. Two codes were added to allow Medicare reimbursement for total shoulder replacement. Codes were also added to allow Medicare reimbursement for total ankle replacement. Additional surgical codes pertained to hip tendon incision and meniscal knee replacement.

Prior to the final payment rule being issued, the Ambulatory Surgery Center Association (ASCA) advocated for the addition of total shoulder arthroplasty to the ASC payable list. Advocacy included a virtual meeting in October 2023 between ASCA representatives and Doug Jacobs, M.D., chief transformation officer of the Center for Medicare at CMS. During the meeting, questions were raised as to why total shoulder arthroplasty was not on the list while total knee arthroplasty and total hip arthroplasty were on the list.

In an ASCA press release, ASCA Chief Executive Officer Bill Prentice expressed gratitude, stating, “We thank CMS for



Source: Pixabay and Sammy-Sander

heeding our request to move additional surgical procedures—including total shoulder arthroplasty—onto the ASC payable list.”

Prentice continued, “Doing so benefits both Medicare beneficiaries, who now have a lower-cost choice for the care they need, and the Medicare program itself, which will save millions of dollars as volume moves to

the high-quality surgery center site of service.”

CMS also updated Outpatient Prospective Payment System payment rates for certain hospitals and ASCs by 3.1%. According to a CMS fact sheet, “This update is based on the projected hospital market basket percentage increase of 3.3%, reduced by a 0.2 percentage point for the productivity adjustment.” ♦

Former NUVA and LimaCorporate Exec Takes Top Job at OFIX

BY ROBIN YOUNG



Massimo Calafiore / Courtesy of Orthofix Medical Inc.

Massimo Calafiore, the former chief commercial officer for NuVasive, Inc., responsible for all NUVA product marketing and commercial functions, and the current CEO of Villanova, San Daniele del Friuli, Italy-based LimaCorporate—a supplier of products for total hip and knee arthroplasty, revision cases and other musculoskeletal fixation indications—has accepted the top job at Lewisville, Texas-based Orthofix Medical Inc.

Calafiore's current company, LimaCorporate, is being bought by Wilmington, Delaware-based Enovis Corporation.

First Reaction – Great Fit – Company to CEO and Vice Versa

Orthofix has operations in Italy, sells products in multiple musculoskeletal markets and has a major investment in spine—all areas where Calafiore has operated at the top ranks of this industry.

At his current post, Calafiore strengthened and reshaped the LimaCorporate's strategy and culture priorities—resulting in consecutive quarter-over-quarter above-market growth, strong EBITDA margins, and substantial

improvement in employee engagement and retention.

On September 25, 2023, roughly one year after Calafiore became CEO, LimaCorporate announced its sale to Enovis Corporation for €800 million.

At NuVasive, Calafiore brought the Ellipse technology (an OTW Best Technology in Spine Award Winner) into the company, delivered multiple quarters of sequential sales growth, profit margin expansion, and made NuVasive a market leader in the complex trauma and

I like the idea that, at Orthofix, all the levers are in place to build the next billion-dollar medical device company.

limb recon markets for adults and children—one of Orthofix’s primary markets as well.

Before NuVasive, Calafiore rose through the ranks at Waldemar Link GmbH & Co, which developed several legendary orthopedic, lower extremities and spine products. He later oversaw the sale of the STAR Ankle to the Viscogliosi Brothers and Small Bone Innovations Inc. and then the PCM Cervical disc to NuVasive.

Calafiore holds an M.Sc. in Mechanical Engineering from the University of

Catania and an MBA from New York University.

Second Reaction – Buyers Seem to Like the Companies He Leads

First, Globus Medical, Inc. bought NuVasive out from under him, now Enovis is buying LimaCorporate.

OTW was able to catch up with Calafiore while he was still in Italy, managing LimaCorporate and its integration into Enovis. We asked him about coming to Orthofix. He said it is the pinnacle of his career—as if everything he

did before, was preparing him for this new post.

He is excited. “I like the idea that, at Orthofix, all the levers are in place to build the next billion-dollar medical device company.”

Orthofix was founded decades ago as an Italian fixation business, owned by a British group, and based initially, believe it or not, in the Netherlands Antilles.

Massimo is Italian and has worked in medicine his entire life.

Coming to Orthofix

As he told OTW, “Orthofix has a solid financial platform—strong balance sheet, strong cash flow generating products and, in both SeaSpine and Orthofix proper, excellent prod-

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JAMES D. MITCHELL, MD

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uct lines and staff.” But more than that, he told *OTW*, the company has several high cash generating products combined with top of class spine systems—notably 7D imaging, SeaSpine’s industry leading biologic portfolio and its broad range of recon fixation and spinal implants and instrumentation.

Calafiore won’t take the corner office at Orthofix until early 2024, after Enovis completes the purchase of LimaCorporate.

Catherine Burzik, chair of the board of directors and interim CEO of Orthofix, said “Massimo is the right choice to lead Orthofix given his exceptional track record of delivering value creation and his extensive knowledge of the medical device industry, specifically within orthopedics and spine.”

“Throughout his career, Massimo has demonstrated his ability to unlock value opportunities for multi-segmented, global businesses. He has successfully driven sales and commercial operations to achieve both industry leading profitability and growth. Importantly, he has proven experience integrating companies and building high performing teams.”

Burzik, in conjunction with the announcement that Massimo Calafiore will be leading Orthofix, also said that she will be stepping down as Orthofix’s board chair.

Calafiore issued the following statement, ““Having worked in orthopedics and spine throughout my entire career, I know Orthofix well and have long admired the Company and its talented team.”

“I was attracted to Orthofix given the many growth opportunities created by its unique, broad-based portfolio and high-quality distributor relationships. I am also impressed with the innovative solutions Orthofix has developed to meet the needs of surgeons and the patients it serves. At this pivotal time for the Company, I look forward to working with the Board and leadership team to capture Orthofix’s significant profitable growth potential and drive enhanced shareholder value.”

Finally, a word about Calafiore’s management style. It hasn’t changed since his days at Waldemar Link. He is an inclusive style of manager whose strengths are team building and focus—specifically on the three “bests”: best technology, best service, and best culture for employees, patients, surgeons, and last, but never least, shareholders. ♦



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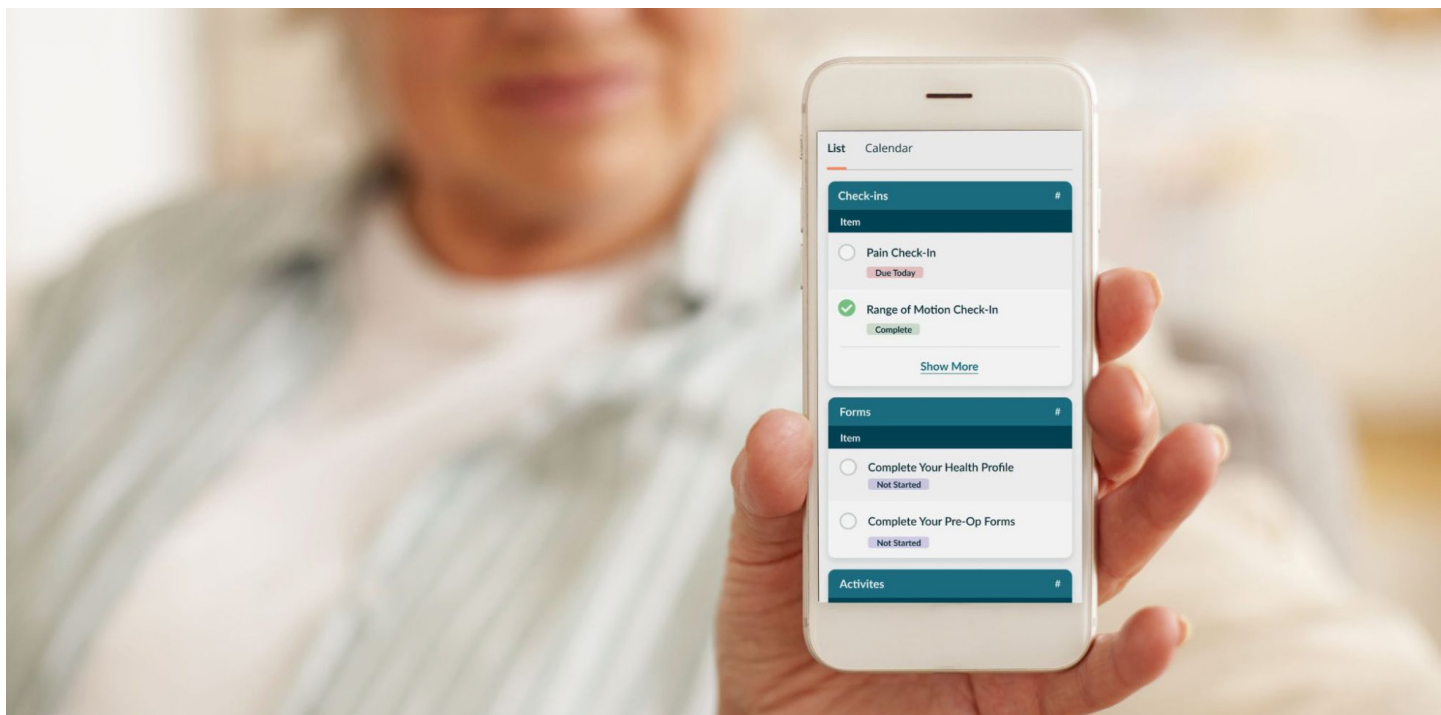
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Remote Patient Monitoring Wins AAHKS's 2023 Innovation Award

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



Courtesy of Force Therapeutics LLC

Remote patient monitoring, one of the great promises of the digital revolution in medicine, was chosen from a field of 16 submissions and won the prestigious Industry Innovation Award by the American Association of Hip and Knee Surgeons (AAHKS) at the organization's recent annual meeting in Dallas, Texas.

The company that developed this digital technology, 13-year-old, New York City-based Force Therapeutics LLC, was founded by a former physical therapist with more than 20 years of clinical physical therapy experience. The founder, Bronwyn Spira, understood the challenges for patients who

had been sent home with vague care instructions and stick figure drawings, but ended up struggling with recovery at home. Her belief, and it is the reason she founded Force Therapeutics, is that empowering patients with the right education and communication can take a lot of cost out of the system and, most importantly, improve patient outcomes.

Amen.

"AAHKS is truly excited to grant the Industry Innovation Award to Force Therapeutics for its addition of Remote Therapeutic Monitoring (RTM) to its digital care platform. It's very important for industry to have a role in developing

innovations in patient care and with 16 entries submitted, I think that's a great indicator for innovation in the field of hip and knee arthroplasty," said Javad Parvizi, M.D., FRCS, AAHKS President.

Company CEO Bronwyn Spira told OTW, "At Force Therapeutics, our mission is to improve patient outcomes and provider efficiency while reducing the overall cost of care."

"As the leading MSK patient engagement platform, Force Therapeutics is uniquely equipped to optimize digital care and RTM reimbursement, resulting in strong patient outcomes and satisfaction, while reducing costly barriers,

improving access to care and optimizing provider workflows.”

“The 2023 AAHKS Industry Innovation Award is validation that our advanced platform innovations continue to provide high quality improvements for both patients and surgeons and is in sync with what the Orthopedic market needs.”

“Our RTM solution allows health systems, physician practices, and ambulatory surgical centers to provide patients with virtual physical therapy and remote monitoring that adheres to CMS [Centers for Medicare and Medicaid Services] guidelines. Our provider-prescribed digital care management platform is validated to provide compliant documentation for the new RTM Current Procedural Terminology (CPT) codes finalized by the Centers for Medicare and Medicaid Services,” added Spira.

Our system engages both patients and providers, enabling robust real-time data collection and actionable insights to produce the most effective patient care and the most efficient provider workflows possible.

“It is a powerful tool, with deep clinical intelligence, that scales workflows and maximizes care teams to drastically improve efficiency, profitability, and set a new standard of high-quality care.”

Finally, said Spira, “Our system engages both patients and providers, enabling robust real-time data collec-

tion and actionable insights to produce the most effective patient care and the most efficient provider workflows possible. By automating routine touch points and tasks, Force Therapeutics enables clinical care teams to intelligently monitor and interact with patients throughout their care journey.” ♦

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COMPANY

HOPCo Expands in Connecticut

Phoenix, Arizona-based Healthcare Outcomes Performance Company (HOPCo) has just closed its second significant transaction of 2023 and, since its founding in 2005, has partnered with or acquired a significant number of musculoskeletal care practices.

HOPCo is now one of the largest musculoskeletal care providers in the United States with more than 1,100 care providers in 30 U.S. locations.

Its most recent transaction is a partnership with OrthoConnecticut, one of the largest musculoskeletal multi-specialty practices in Connecticut with 48 musculoskeletal providers and 9 locations.



Courtesy of Healthcare Outcomes Performance Company and OrthoConnecticut

It was created from the merger of Coastal Orthopedics, Danbury Orthopedics, New Milford Orthopedics, and Connecticut Pain Care.

OrthoConnecticut President Michael Brand explained, “Our intention to join forces and become OrthoConnecticut was always to combine best practices so as to provide the best possible outcomes and experience for our patients.”

Dr. Brand continued, “Now that we have consolidated into one platform, we knew we would benefit from an experienced partner that could provide a proven infrastructure for continued growth and accelerated market transformation. We witnessed how HOPCo helped enhance practices similar to ours with the value they bring, so we knew they were the best choice as a partner.”

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HOPCo is a leading healthcare management company. Its strategic objective is to partner or acquire orthopedic or spine practices and give them access to “HOPCo’s proprietary suite of MSK Service Line Transformation offerings.”

According to the company, HOPCo “develops and manages highly successful MSK value-based care models, including full MSK population health programs that have proven to improve outcomes and access for patients while dramatically lowering the total cost of MSK care.”

Just a couple months before announcing the OrthoConnecticut partnership, HOPCo acquired Florida-based Institute for Orthopaedic Surgery & Sports Medicine.

HOPCo President and Chief Transformation Officer Wael Barsoum, M.D. discussed

the partnership. Dr. Barsoum stated, “OrthoConnecticut is a shining example of a practice that is leading the transition to value-based care in their market.”

Dr. Barsoum continued, “Their decision to become OrthoConnecticut signaled to the community their commitment to expanding access to excellent care. Now that they have partnered with HOPCo, we aim to help them accelerate their growth, improve outcomes and reduce costs for patients and payors while still providing unparalleled patient access and personalized care.”

Jason Scalise, M.D., Chief Growth Officer at HOPCo, spoke to OTW about HOPCo’s continued growth. Dr. Scalise elaborated, “HOPCo has seen tremendous growth both nationally and internationally. In just the last few years alone, we have completed dozens of acquisitions and partnerships in

various areas, including MSK physician practices, hospital service lines, ambulatory surgical facilities and specialty hospitals, clinically integrated and value-based care networks and innovative technology platform acquisitions.”

Dr. Scalise continued, “HOPCo has partnerships in over 30 states and includes over 1,100 MSK providers across more than 100 office locations. Each provider shares HOPCo’s mission and vision of transformative practice growth and to lead MSK value-based care efforts for their region.”

What’s next for HOPCo? According to Dr. Scalise, “We expect to see continued growth in 2024 and already have several partnerships we will announce in the coming months. These new partnerships will expand our platforms in current markets and also add new markets to the HOPCo footprint.” — KD

Hello New Year!



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- ✔ 6 HTML Email ads
- ✔ 8 Social Media Pushes
- ✔ 2 Web ad
- ✔ 6 Newsletter Ads

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NEW YEAR EXTRAVAGANZA PRICE

\$1,638

BEST

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- ✔ 12 Social Media Pushes
- ✔ 3 Web ad
- ✔ 9 Newsletter Ads

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Online Sports Med Provider Partners With Virtual Ortho Platform

SportsMD.com, an online sports medicine resource, has partnered with ViewFi, a virtual orthopedic and rehabilitation platform.

Millions of children and teens in the United States sign-up for and play organized sports every year. The partnership aims to bring virtual orthopedic sports medicine care to those young athletes.

Andy Roddick is a former professional tennis player and co-founder of ViewFi. In the press release, Roddick commented, "ViewFi and SportsMD are aligned in our commitment to change how sports medicine care is delivered.



Courtesy of SportsMD.com and ViewFi

Athletes of all abilities and youth sports participants will receive the same best-in-class care that I used to get as a professional athlete. This is a differentiator for us and for SportsMD."

Roddick continued, "As a player, I would have to travel long distances for care. We're changing that and our world class doctors are able to diagnose and recommend an appropriate treatment plan, prescribe medications, order and review advanced imaging, or

order physical therapy, from their home and all within two days."

The partnership provides a number of services for athletes. SportsMD powered by ViewFi will offer young athletes the opportunity to be virtually evaluated by sports medicine orthopedic physicians. The physicians will be able to provide, "a comprehensive diagnostic exam virtually, in less than two days." This is a significant advantage when compared to the industry average wait time to see

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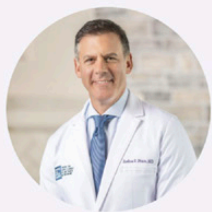


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MD**

Professor Orthopedic
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Josh Dines, MD

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**Asheesh Bedi,
MD**

Clinical Professor
University of Chicago,
Team Physician



**Jocelyn
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Sports Medicine
Orthopedic Surgeon,
Duke University



**Alex Vaccaro,
MD, PhD, MBA**

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Courtesy of SportsMD.com

an orthopedic provider which is, per the press release, 16.9 days.

ViewFi has a technology platform that provides a number of tools to aid in diagnoses. This includes “artificial intelligence-enabled motion-detecting

technology to better track body movement.”

The orthopedic providers on the service will be able to utilize this technology when helping individuals seeking orthopedic care. The providers will

have the support of Hospital for Special Surgery and have a broad range of orthopedic expertise.

Here are some of the physicians who participate in the ViewFi network. — KD



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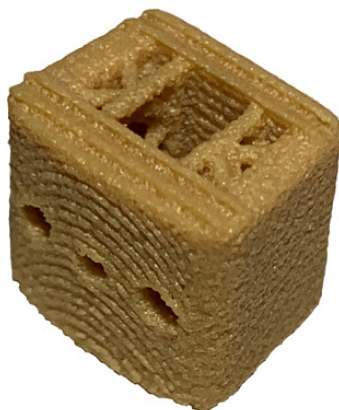
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LEGAL

FDA Clears Novel Cervical Intervertebral PEKK Implant

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to a novel cervical intervertebral body fusion system based on a new material, OXPEKK.

According to its supplier, VySpine™, LLC, the new system, brand named ClariVy OsteoVy™ PEKK, provides better osseointegration than PEEK (polyether-ether-ketone) which has been demonstrated through in vitro and in vivo studies utilizing animal models. PEKK (polyetherketoneketone) also allows manufacturers to create porous shapes which facilitate bone ingrowth



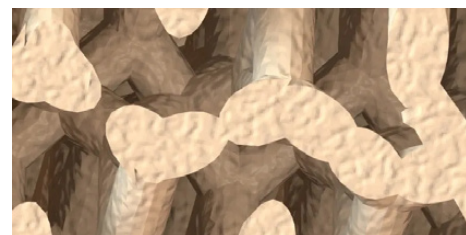
ClariVy™ Cervical IBF System
Source: VySpine™, LLC

while also providing polymer's signature lack of radiographic interference and biocompatibility, meaning no fibrotic tissue membrane formation.

According to the FDA 510(k) summary document, the ClariVy Osteo Vy™ sys-

tem is indicated for "intervertebral body fusion of the spine in skeletally mature patients." The systems are designed for "use with autogenous bone graft to facilitate fusion" and "one device may be used per intervertebral space."

Additionally, the implants are intended to be used with "legally cleared supplemental spinal fixation cleared for the implanted level," namely, at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerate disc disease (DDD is defined as neck pain of discogenic origin with degeneration

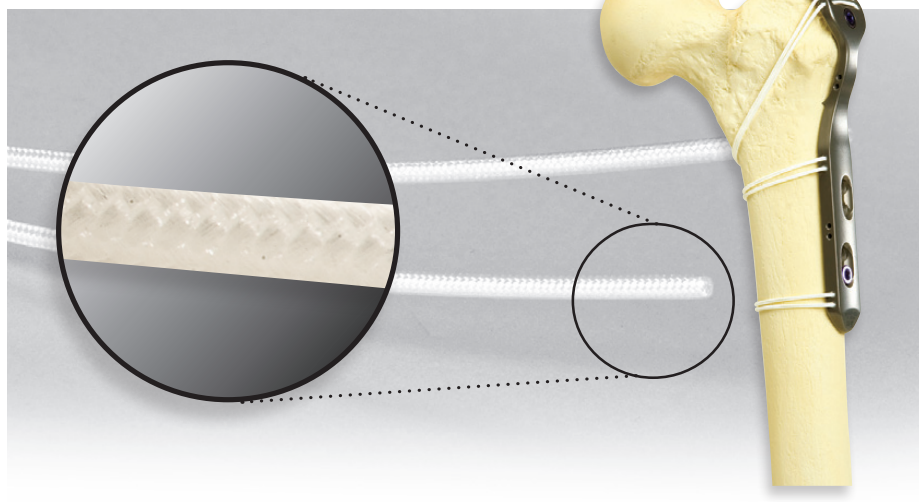


OXPEKK / Source: VySpine™, LLC

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of the disc confirmed by history and radiographic studies).”

It is to be used in patients who “have six weeks of non-operative treatment.”

The device is called the ClariVy™ Cervical IBF System. In order to qualify for 510(k) clearance, the device must be substantially equivalent to a predicate device. The ClariVy Cervical IBF System is substantially equivalent to the primary predicate device of the same name in terms of “material, intended use, levels of attachment, size range, and use with supplemental fixation.”

The ClariVy OsteoVy™ PEKK Cervical IBF System is different from the primary predicate device because it utilizes OXPEKK material. VySpine submitted the device for 510(k) clearance. According to the company, “PEKK

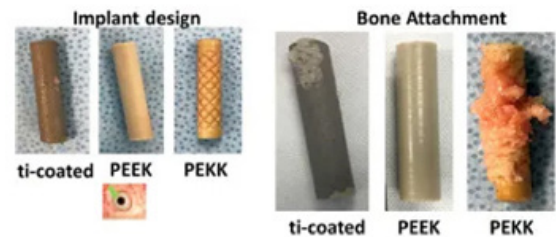
(unlike PEEK) implants demonstrate bone ingrowth, no radiographic interference, no fibrotic tissue membrane formation, significant increase in bony apposition over time, and significantly higher push-out strength compared to standard PEEK.”

VySpine President of Product Development Bret Berry stated, “The ClariVy OsteoVy PEKK clearance is the first in a long line of VySpine implants which will utilize the unique qualities of our proprietary OsteoVy PEKK designs.”

Berry continued, “As we researched OXPEKK and its unique characteristics, we began to realize that its composition accomplishes what we as an industry had always

hoped PEEK would accomplish. But PEEK fell short. We are very excited about the OXPEKK material and our partnership with Oxford Performance Materials to make this new device possible.”

Specifically, PEKK provides higher push-out strength compared to standard PEEK and, as noted earlier, bone growth characteristics comparable to Ti-coated PEEK with significant improvements in implant integrity and radiographic properties. — KD



Bone growth / Source: VySpine™, LLC

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LARGE JOINTS

AAHKS Young Investigator Awarded to Infection Research Team

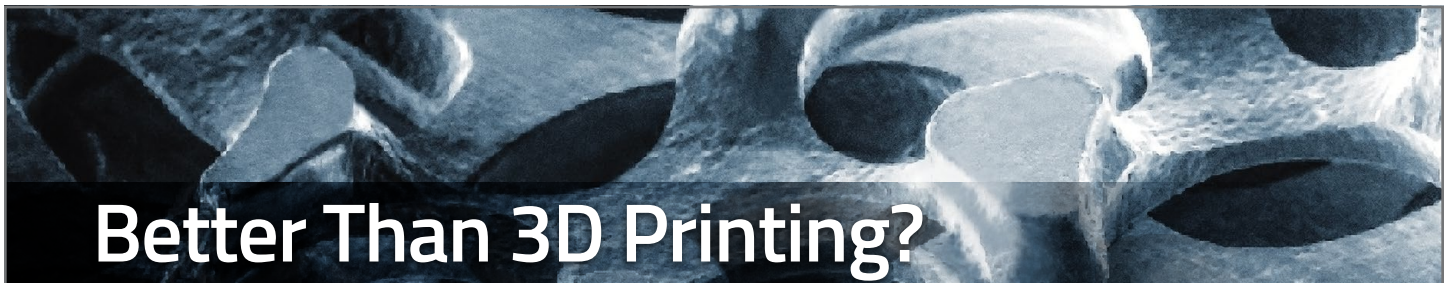
The 2023, James A. Rand, MD, Young Investigator's Award, which recognizes young investigators who demonstrate clinical excellence in knee-related research was presented at the recently concluded American Association of Hip and Knee Surgeons (AAHKS) annual meeting to lead author Jason Kreinices, B.S. and co-authors Ittai Shichman, M.D., Mackenzie A. Roof, M.D., M.B.A., Hayley Raymond, B.S., Alana Prinos, B.S., Itay Ashkenazi, M.D., Ran Schwarzkopf, M.D., M.Sc. and Vinay K. Aggarwal, M.D.



Vinay K. Aggarwal MD Presenting the Award-Winning Study at AAHKS / Courtesy of Anne Cohen-Rosenblum

Their award-winning study explored the effectiveness of diagnostic testing for periprosthetic joint infection (PJI). In their study, the research team collected data for patients who had received revision total hip arthroplasty (THA) or total knee arthroplasty (TKA) for suspected PJI between 2018 and 2020 (minimum two-year follow-up).

They collected perioperative data and lab results, and dichotomized cases based on whether they met the 2018 Musculoskeletal Infection Society (MSIS) criteria for PJI. In total, 204 revision total knee arthroplasty and 158 revision total hip arthroplasty cases suspected of PJI were reviewed.



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The researchers determined that nearly 100% of the cases met the 2018 MSIS criteria for being “infected”—without having to use an alpha-defensin or synovial CRP (C-reactive protein) test.

“The most important thing is to remember that clinical suspicion of infection should guide the workup. Ideally, when possible, an algorithmic approach to the workup is recommended and we found in our paper that using the ESR [erythrocyte sedimentation rate], CRP, synovial WBC [white blood count], PMN [polymorphonuclear neutrophil] and cultures are sufficient to diagnose PJI in more than 96% of cases,” said Vinay K. Aggarwal, M.D., an assistant professor in the department of orthopaedic surgery at the New York University Grossman School of Medicine.

Alpha Defensin Synovial Testing Less Effective Than Expected

“I would emphasize that there was significant early enthusiasm for the alpha defensin synovial testing for periprosthetic joint infection,” stated Dr. Aggarwal to *OTW*. “Some of this enthusiasm has now waned with recent data including in our own study. This is why we felt it was important to highlight that some of these extraneous tests that are new or are not required to proceed with periprosthetic joint infection diagnosis.”

“Furthermore, I do not think it was a surprise to us that nearly 100% of our potential infection cases could be diagnosed using the 2018 criteria without the use of synovial alpha defensin and or synovial CRP. This is what drove the impetus for the study in general given our own experience with not having to use this workup on the majority if not all of the cases.”

“We want to highlight and get the word out that some of this testing can go by the way-

side if you stick to classic clinical suspicion and readily available low-cost testing.”

Employing the Stepwise Algorithmic Approach

OTW asked Dr. Aggarwal for details about the stepwise algorithmic approach. He said, “A stepwise algorithm in our practice for periprosthetic joint infection always starts with a high index of clinical suspicion.”

“This would include a patient who had a previously well-functioning joint replacement and now has pain, swelling, redness that was not there before. Obviously in the acute postoperative phase significant drainage that is not resolving, wound issues, or worsening swelling and pain would also spark a workup.”

“Thereafter we start with simple laboratory testing including ESR and CRP. If either of these is elevated in our practice, we turned towards a synovial aspiration where we sent testing for cultures and cell count that includes white blood cells and polymorphonuclear differential (PMN%).”

“This workup is capable of diagnosing periprosthetic joint infection in the vast majority of cases. Occasionally we need additional intraoperative culture data to confirm the suspicion and with these combined we were able to achieve nearly 100% diagnosis rate in our study.”

“The biggest issue with cost is in relationship to individual hospital contracts with laboratory testing,” stated Dr. Aggarwal to *OTW*. “With the above test that I have mentioned the cost is so low that it is almost not necessary to keep an eye on them. When you start to introduce new technology and newer testing without a standardized approach this is where costs can elevate, and practice deviation of protocol leads to less than necessary or acceptable expenditures.” — *EH*

PEOPLE

OREF/UConn to Support Laurencin Regenerative Engineering Institute

The Orthopaedic Research and Education Foundation (OREF) and the UConn Foundation are teaming up to support The Cato T. Laurencin Institute for Regenerative Engineering at the University of Connecticut (UConn).



Cato T. Laurencin, M.D., Ph.D.
Courtesy of UConn Health

The field of regenerative engineering is the brainchild of Cato T. Laurencin, M.D., Ph.D., the University Professor and Albert and Wilda Van Dusen Chair in Academic Medicine Distinguished Endowed Professor of Orthopaedic Surgery at UConn. Funds raised by OREF, and the UConn Foundation will support the core programs of The Cato T. Laurencin Institute.

Dr. Laurencin told *OTW*, “I am very happy to see the pace in which this partnership has been formed to advance

the field of Regenerative Engineering that I founded. This is a first of a kind partnership which is really centered on bringing new technologies and solutions to benefit patients.”

Dr. Laurencin is the first surgeon elected to the four national academies: the National Academy of Sciences, the National Academy of Engineering, the National Academy of Medicine, and the National Academy of Inventors. In orthopedic surgery, Dr. Laurencin is the first to receive the American Orthopaedic Association's Distinguished Contributions to Orthopaedics Award, the Nicholas Andry Lifetime Achievement Award from the Association of Bone and Joint Surgeons, the Kappa Delta Award from the American Academy of Orthopaedic Surgeons, and the Marshall R. Urist Award from the Orthopaedic Research Society.

Dr. Laurencin has outlined regenerative engineering as the convergence of advanced materials science, stem cell science, physics, developmental biology, and clinical translation, for the regeneration of complex tissues and organ systems. The groundbreaking work of Dr. Laurencin includes the launch of the Hartford Engineering a Limb (HEAL) Project aimed at regenerating whole limbs. Dr. Laurencin has been honored with the National Medal of Technology and Innovation, America's highest honor for technological achievement, given in ceremonies at the White House. Dr. Laurencin is the 2023 Inventor of the Year, named by the Intellectual Property Owner's Education Foundation.

“We started the Hartford Engineering a Limb Project with the goal of regenerating whole limbs in humans. To make

this happen we will need expanded resources for The Cato T. Laurencin Institute for Regenerative Engineering,” stated Dr. Laurencin to OTW. “It is gratifying to see OREF, and the University of Connecticut Foundation embrace our vision.”

“The Cato T. Laurencin Institute for Regenerative Engineering brings together an array of vital domains integrating medicine, engineering, surgery, biology, physics, chemistry, and statistics/machine learning to enable a powerful platform for addressing scientific and medical problems in the regeneration and healing of complex tissues, organs, or organ systems. This new partnership is exciting. It will advance clinical treatment and patient outcomes through novel research, and through translating findings directly to technologies helping people.” — EH

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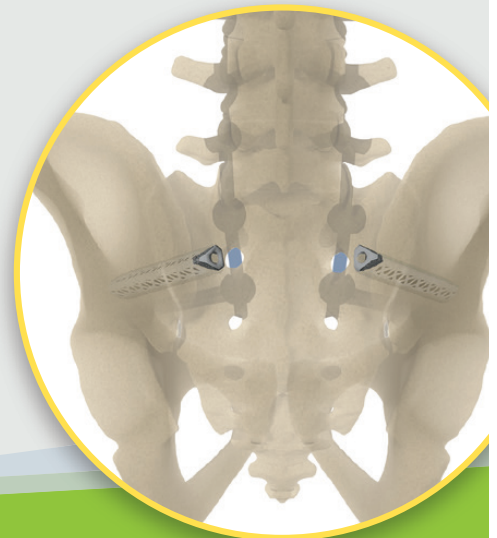
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* de Andrade Pereria B, et al. *J Neurosurg Spine*. 2021 Jun 18;1-10. doi:10.3171/2020.11.SPINE201540.

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REMEMBRANCE

Famed Little Rock Ortho Surgeon, Austin Grimes, Dies at age 94

Dr. Harry Austin “Steno” Grimes did not originally choose medicine as a career. In 1946, while still a high school student (and president of his senior class), Harry Grimes set his sights on becoming an ace fighter pilot. He had received flight training at Newport Auxiliary Airfield and his pilot’s license at age 16.

Indeed, after graduating from the University of Arkansas Medical School in 1955 (and interning at Jackson Memorial Hospital in Miami) he joined the United States Air Force, achieving the rank of captain and graduating from Flight Surgeon School at Randolph AFB.

Dr. Grimes was assigned to the 19th Bomb Wing at Homestead AFB (in Florida) and was, at one point, sent to interesting temporary duty at Ben Guerir Air Base, Morocco.

Following his tour of duty, Dr. Grimes returned to Jackson Memorial for three more years of resident training in general and orthopedic surgery, but Uncle Sam was not finished with him—Dr. Grimes was recalled to provide air support for the Bay of Pigs affair and stayed for a short while, basing out of Barksdale AFB in Shreveport, Louisiana.

Following that service, Dr. Grimes moved to and settled permanently in Little Rock, Arkansas, where he and two colleagues founded the Little Rock Orthopedic Clinic and, later, served as president of the Little Rock Academy of Surgery.



Harry Austin “Steno” Grimes, M.D. / Courtesy of Ruebel Funeral Home

Dr. Grimes served the patients of Little Rock and surrounding communities for more than a quarter century. Influenced by Viktor Frankel's book, Dr. Grimes practiced medicine as both an art and a science. Even after his ‘retirement’ at age 65, Dr. Grimes continued to see patients and volunteered in St. Vincent's free clinics until retiring from medicine at age 70.

Dr. Grimes also had another remarkable skill—drawing anatomy. After retiring from medicine, he took his first-ever art lessons at the Arkansas Art Center and then continued to study under oil painter Barry Thomas, who encouraged him to paint what he saw despite being colorblind.

Dr. Grime’s art has been displayed in local galleries, at art shows in Newport and was chosen for CareLink’s first local holiday card and for calendars of the Arkansas Governor’s Mansion Association and CARTI, where he eventually underwent 12 years of cancer care.

Harry Austin Grimes was born in 1928. The future Dr. Grimes grew up working in his parents’, Aarol and "Annie," drug store during the Great Depression

in Arkansas. He earned an Eagle Scout designation and achieved the Order of the Arrow.

As he often related to his friend, the old men of Newport taught him the game of golf during World War II, a sport he enjoyed for almost eight decades.

Dr. Grimes shot his fifth and sixth holes-in-one at age 82.

Dr. Grimes volunteered as a subject in the Physicians' Health Studies I and II, beginning in 1982 and 1997 respectively, which tested the benefits and risks of aspirin, beta carotene, vitamins E and C, and multivitamins. He later volunteered in the Cocoa Supplement and Multivitamin Outcomes Study (COSMOS), where results are still being studied.

Austin is survived by his wife Ann Grimes, daughter Meredith McLeod, stepson Adam Wells, close-to-heart niece Bridget Rogers and nephew Seth Schulte, and cousins in Arkansas and California. He was predeceased by his parents, daughter Mardi DeBerry, stepson Patrick Wells, and step-daughter-in-law Jana Wells. — TR



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