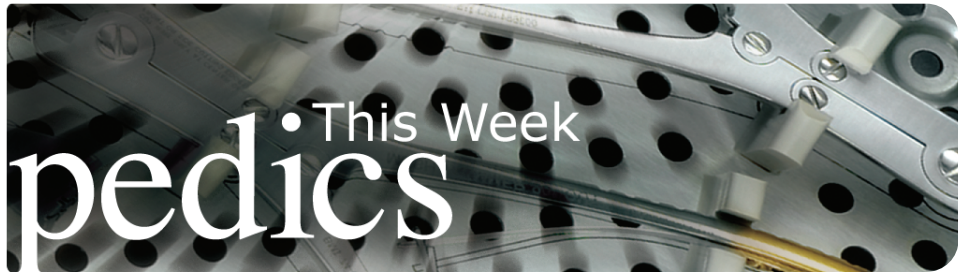


Ortho



WEEK IN REVIEW

4 Old Spines, Need New Ideas: Spine Hardware Update >> In strong, non-osteoporotic bone, pedicle screw loosening rates are about 1-15%. In osteoporotic bone those rates soar to more than 60%. Old spines need new ideas. Time for Karma, a better approach for spine fixation when bone quality is suspect.

8 Ortho CEO and Doctor Save Shark Attack Victim >> Friday, June 7, 2024, started like any other sunny, calm day on one of Florida's Gulf Coast beaches. Families relaxing. Swimmers frolicking in the clear, warm waters. Then everything changed and two unconnected members of the orthopedic community—a CEO of a start-up orthopedic supplier and an orthopedic surgeon went into ER mode and saved the life of a shark attack victim.

12 The Smartest Guys in Spine Are Buying ATEC Stock >> Two of the most successful CEOs in the history of spine surgery, Keith Valentine, former CEO SeaSpine and NuVasive, Inc, and David Demski, former CEO of Globus Medical, have both stepped up and bought more shares of Alphatec Holdings, Inc. (ATEC).



BREAKING NEWS

- 13 **Globus Sales Hit \$630 million, up 116%**

- 17 **Patient Compliance App Receives MedTech Breakthrough Award**

- 20 **Is SpineFrontier's Legal Saga Settled?**

- 20 **Nine NEW Shoulder Arthroplasty Patents Issued**

- 21 **Medicare Death by a Thousand Payment Cuts? AMA Pushes Back!**

- 23 **Kris Alden, M.D., Ph.D., Joins The Steadman Clinic**

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: Investors were not kind to companies who missed their mid-year, 2024 profit expectations. Four, in particular, took it on the chin: Pacira down 42%, Alphatec down 41%, Integra down 26% and Nevro down 25%. Investors were scaling the Wall of Worry—mideast wars, rising U.S. unemployment and the Fed's measured approach to lowering interest rates (why is that a surprise?). So conditions were ripe for emotional over reactions. In times like these, the Wall Street adage is "watch what insiders do." In ATEC's case, two of the smartest guys in spine, who happen to be ATEC insiders, bought more stock. Still. Message received. Investors want growth companies to turn a profit sooner than later.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Smith & Nephew	14.46%	5.85%	Investors really like SNN. Since June, when the massive Swiss investment bank UBS raised its rating, SNN's stock up 18%. Helping is a new hip system and AI deal with HOPCo.
2	3	Globus Medical	13.71	5.43	GMED's senior management may not be entirely happy with operating margins, but investor sure like this trend. Q2 sales up over 100% and new knee system announced. Yes, KNEE.
3	8	Bioventus	4.34	28.86	New CEO Claypoole reported 14% sales growth and 41% increase in cash from operations for Q2. Music to investors' ears. Still comparatively cheap. But up almost 29% in 30 days.
4	NR	Johnson & Johnson	20.78	7.49	Back on the Power Rankings after an extended absence. 9th best valuation and 5th best stock performance. DePuy Synthes grew worldwide knee sales 9.5%, highest of all. Accumulating market share overall.
5	9	Medtronic	19.17	6.46	MDT spine has a new energy and focus. Senior management Skip Kill and Michael Carter creating excitement and sense of purpose. MDT spine is gathering momentum.
6	10	ConMed	9.63	2.79	ConMed is probably one of our most consistent value companies on the Power Rankings. Q2 report was decent, but CNMD remains 4th cheapest stock in Ortho.
7	5	Orthofix	(16.17)	8.31	The headline for OFIX's 2nd quarter report was 138% earnings surprise. Wall Street forecast \$0.13 per share loss. Then CEO Massimo reported a PROFIT of \$0.05 per share.
8	2	Integra LifeSciences	10.98	(25.62)	Wall Street is an emotional, irrational place. For Q2, IART beat sales forecasts. \$418mm vs \$413mm estimated. Also beat EPS estimates. Yet, down 26% and now 2nd cheapest Ortho stock.
9	NR	Zimmer Biomet	20.70	1.10	Agrees to buy large joint AI company OrthoGrid Systems. FDA cleared applications, 40 patents, exciting young company—now part of ZBH's global orthopedic distribution platform.
10	7	Medacta	13.00	10.02	Strong buying interest in an otherwise bear-ish market. This Swiss-based orthopedic company is one of the most innovative and fast growing, well capitalized companies on the Power Rankings.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	AxoGen	AXGN	\$11.02	\$483	43.12%
2	Bioventus	BVS	\$7.59	\$615	28.86%
3	Medacta	MOVE	\$148.29	\$2,966	10.02%
4	Orthofix	OFIX	\$16.17	\$617	8.31%
5	Johnson & Johnson	JNJ	\$160.62	\$386,651	7.49%
6	Medtronic	MDT	\$82.04	\$105,197	6.46%
7	Smith & Nephew	SNN	\$29.87	\$13,058	5.85%
8	Globus Medical	GMED	\$73.20	\$9,908	5.43%
9	Aurora Spine	ASG.V	\$0.21	\$16	4.69%
10	SI-BONE, Inc	SIBN	\$13.98	\$583	3.17%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Pacira Biosciences	PCRX	\$11.70	\$540	-42.48%
2	Alphatec Holdings	ATEC	\$6.31	\$886	-41.41%
3	Integra LifeSciences	IART	\$21.80	\$1,691	-25.62%
4	Nevro Corp	NVRO	\$6.01	\$224	-24.97%
5	OrthoPediatrics Corp	KIDS	\$26.91	\$652	-15.32%
6	Dynatronics Corp	DYNT	\$0.17	\$1	-12.87%
7	SINTX Technologies	SINT	\$4.40	\$3	-11.65%
8	Aclarion	ACON	\$0.28	\$2	-7.57%
9	Xtant Medical Hldgs	XTNT	\$0.62	\$81	-7.31%
10	Stryker	SYK	\$327.83	\$124,928	-2.82%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	\$11.70	\$540	9.15
2	Medtronic	MDT	\$82.04	\$105,197	19.96
3	Johnson & Johnson	JNJ	\$160.62	\$386,651	20.24
4	ConMed	CNMD	\$67.07	\$2,068	23.92
5	Integra LifeSciences	IART	\$21.80	\$1,691	24.97

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Xtant Medical Hldgs	XTNT	\$0.62	\$81	122.61
2	Globus Medical	GMED	\$73.20	\$9,908	60.13
3	Medacta	MOVE	\$148.29	\$2,966	57.84
4	Smith & Nephew	SNN	\$29.87	\$13,058	49.65
5	Stryker	SYK	\$327.83	\$124,928	33.05

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	\$29.87	\$13,058	-6.21
2	Pacira Biosciences	PCRX	\$11.70	\$540	0.85
3	ConMed	CNMD	\$67.07	\$2,068	1.25
4	Medacta	MOVE	\$148.29	\$2,966	2.07
5	Stryker	SYK	\$327.83	\$124,928	2.93

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Xtant Medical Hldgs	XTNT	\$0.62	\$81	6.13
2	Medtronic	MDT	\$82.04	\$105,197	4.54
3	Integra LifeSciences	IART	\$21.80	\$1,691	3.96
4	Zimmer Biomet	ZBH	\$108.08	\$22,011	3.66
5	Johnson & Johnson	JNJ	\$160.62	\$386,651	3.66

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	\$6.01	\$224	0.53
3	Pacira Biosciences	PCRX	\$11.70	\$540	0.80
4	Aurora Spine	ASG.V	\$0.21	\$16	0.82
5	Orthofix	OFIX	\$16.17	\$617	0.83

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Aclarion	ACON	\$0.28	\$2	30.54
2	Globus Medical	GMED	\$73.20	\$9,908	6.32
3	Stryker	SYK	\$327.83	\$124,928	6.09
4	Medacta	MOVE	\$148.29	\$2,966	5.81
5	Johnson & Johnson	JNJ	\$160.62	\$386,651	4.54

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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Old Spines, Need New Ideas: Spine Hardware Update

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

“Don’t be afraid to give up the good to go for the great.” –John D. Rockefeller

Before you’ve blown out the candles on your 50th birthday cake, your bones have probably started to lose density. That fun fact comes courtesy of the Bone Health and Osteoporosis Foundation. And, you have company—44 million Americans have low bone density—and another 10 million carry an osteoporosis diagnosis.

More than 50 million Americans, many of whom also have back pain, are at increased risk of fracture.¹

When these folks, most of whom are active well into their later years, do have severe back pain, and the best recommendation their doctor can offer is spine surgery, then the problem of relying on osteopenic or osteoporotic bone to secure metal rods and screws rears its ugly head.

Lumbar spine fusion is a well-established standard of care for treating degenerative spondylolisthesis, stenosis and other spine pathologies. While spine fusion success rates are high, between 65-95%, they are not without potential complications.ⁱⁱ

In strong, non-osteoporotic bone, pedicle screw loosening rates are about 1-15%. In osteoporotic bone those rates soar to more than 60%. Old spines need new ideas.^{iii iv}

What would spine fusion look like, particularly in patients with low bone den-



Source: Shutterstock

sity if implant fixation and the resulting spinal stabilization was non-metal?

For starters, probably easier post-op visualization. But, more to the point of this article, as recent studies have demonstrated, less risk of implant loosening in patients with compromised bone quality.

Spine surgeons want to do the right thing, which can also mean doing the familiar thing. But, when the patient is older or diabetic or under a course of care that affects bone quality, then is a big spine fusion surgery where a

mass of metal is deployed to treat spinal stenosis, degenerative spondylolisthesis and perhaps instability, still “the right thing?”

“Probably not,” says Pierce D. Nunley, M.D., founder and director of the Spine Institute of Louisiana. “When it comes time to discuss surgery with my over-65 patients who have spondylolisthesis, low bone mass, and stenosis, I show them a model with the two options: on one side a bulky pedicle screw model, and the other side a metal-free, small zip tie-looking strap made of PEEK.”

“Once they see that, no one wants the metal.”

Fixation and Stability for Older Spines – It’s Karma!

“We have no shortage of patients contending with complications associated with the aging spine,” states Dr. Nunley. “These cases can be particularly complex, so we need evolved solutions such as Karma. This device gives surgeons a sense of confidence that they have a spinal device that addresses the challenges in treating the aging spine patient.

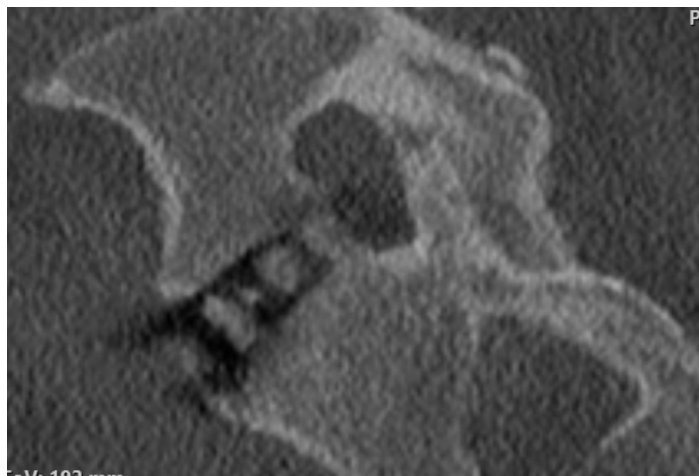
The “this is what you’ve been waiting for” procedural solution—known as the Karma Posterior Fixation System—was designed by the engineers at Spinal Elements to perform in either an open or MIS [minimally invasive surgery] approach.

It’s a low-profile device that successfully stabilizes the spine during the fusion and throughout the healing process. It’s Karma!!

Fusion plus hardware works like a charm—until it doesn’t. The key, we know, is patient selection. Not all patients need metal. Fact is, estimates of lumbar fusion failure rates remain stubbornly in the 30% to 46% range.^v Should it really be called “the gold standard?”

Old Spines Need New Ideas

In 2020, according to the World Health Organization, 619 million people had low back pain, globally.



1-year post-op image showing a solid fusion using Karma. / Source: Spine Institute of Louisiana

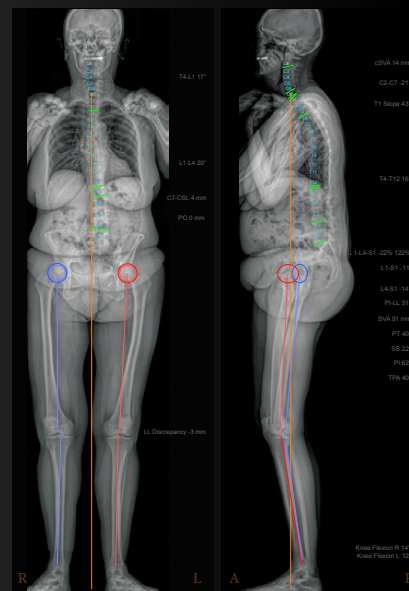
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By 2050, because of aging and population growth, that number could very well rise to as much as 843 million cases.^{vi}

Face it, old spines are a growth industry. Every spine surgeon needs (and patients deserve) rigorously tested and viable options for any patient who presents with life altering back pain yet contends with low bone density.

Anchoring for Stability – It’s Good Karma!

Karma is the first-ever spine fixation device to take advantage of the cortico-pedicular corridor—the densest portion of the spine.

“You get exceptional purchase with Karma because you are drilling through four areas of cortical bone—the part of the spine with the most closely com-

pacted bone,” says Dr. Nunley. “The density of cortical bone is far less effected by age-related degeneration, so surgeons can obtain excellent fixation via good quality, stable bone.”

And with a recent study indicating that cortico-pedicular fixation is safe and reproducible,^{vii} Karma is well-positioned to address the ongoing issues of pedicle screw fixation.

Pedicle fixation plus poor bone quality...What could possibly go wrong?

“Pedicle fixation is imperfect and coupled with bone quality issues, can lead to loosening and implant failure,” adds Dr. Nunley. Indeed, says the research, screw loosening occurs in about 10% of patients, a number that increases to above 60% for osteoporosis patients.^{viii}

Versatile Karma!

According to Terrence Crowder, M.D., an orthopedic spine surgeon with Sonoran Spine in Arizona, there are many indications for a non-metal, low bone density solution.

“First of all, there are legions of people with *degenerative spondylolisthesis* who don’t know they have it, in part because it can take 15-20 years to develop. This is accompanied by a slow onset of lumbar stenosis and neurogenic claudication, and, since it’s slow it is easy to miss because as people age, they think—or are told—that it’s arthritis. Unfortunately, primary care physicians, physician assistants and nurse practitioners are often misdiagnosing these patients. There is a clear educational gap here.”

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“Second, looking at the range of treatments, i.e., from injections to interspinous devices to laminectomy then fusions with posterior screws, I think laminectomy plus Karma provides an ideal solution as it adds a great deal of stabilization, leverages cortical bone, spares tissues, and allows for proper decompression. Karma bridges the gulf between those who do fine with a laminectomy and those who need a fusion that is a less burdensome operative experience.”

“Third, most patients recoil from the thought of a big surgery where they are left with cumbersome screws and rods for the rest of their lives. When patients know there is an alternative, they ask for Karma.”

The Data and Patient Outcomes

“In my experience,” states Dr. Nunley, “Karma is perfect for patients who have up to a grade 2 spondylolisthesis and are not terribly unstable—so a decompression plus Karma is typically in order. Equally, individuals without spondylolisthesis, but with severe stenosis also benefit from this implant.”

“Surgeons are torn between doing a decompression and hoping they won’t have to do a fusion versus jumping straight to fusion...Karma takes that issue off the table.”

Dr. Crowder has had success treating a range of patients using Karma.

“Those with severe leg pain (neurogenic claudication or radiculopathy) and *degenerative spondylolisthesis* are ideal for this device. It’s fantastic that you can do this surgery on an outpatient basis, meaning less blood loss, a smaller incision, and patients can leave the same day. Because this is a less disruptive procedure overall, even some patients with challenging pathologies can have a laminectomy with Karma. In our efforts to ‘do no harm,’ we should consider not putting an older person through a larger-than-necessary surgery.”

Karma’s proprietary curved drill provides circumferential cortical fixation through the lamina, pedicle, and facets. In a recent study, researchers found that among 35 curved holes done with Spinal Elements’ drill, there were no breaches of the anterior cortex. In the finite element analysis study, the Karma provided comparable clinical stability and reduced anterior stress shielding compared to the conventional screw-rod construct.^{ix}

Dr. Nunley: “Karma’s sophistication is based on a ‘perfect storm’ of attributes: it has a small footprint, the incision is small, it uses cortical bone, requires one tray, is radiolucent and involves a patented curvilinear drill that takes a deep dive into the pedicle.”

And this perfect storm of attributes is needed for the perfect storm of aging spines.

Each year in the U.S., osteoporosis leads to roughly 2 million fractures, including 550,000 vertebral fractures.^x Grade 1 spondylolisthesis accounts for 75% of all cases.^{xi} As for lumbar spinal stenosis, it is the most significant cause of spinal surgery in patients over 65 years of age.^{xii}

“Karma is not just another iteration of a procedure or device,” concludes Dr. Nunley. “This is innovation in the true sense of the word—it is disruptive and improves the lives of our patients.”

Old spines need new ideas...fortunately, the sages at Spinal Elements have generated good Karma. ♦

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Ortho CEO and Doctor Save Shark Attack Victim

BY TRACEY ROMERO

Friday, June 7, 2024, started like any other sunny, calm day on one of Florida's Gulf Coast beaches. Families relaxing. Swimmers frolicking in the clear, warm waters. Then everything changed and two unconnected members of the orthopedic community—a CEO of a start-up orthopedic supplier and an orthopedic surgeon went into ER mode and saved the life of a shark attack victim.

The CEO was Alyssa Huffman, of ALLUMIN8, a young and innovative company bringing to market implants which are more bone and patient friendly for orthopedic and spine surgeries. The orthopedic surgeon was Dr. Patrick Toy, M.D., MBA, whose practice is part of the legendary Campbell Clinic Orthopedics in Tennessee.

Like a Scene Out of JAWS

Elisabeth Foley, a 45-year-old wife and mother from Virginia was swimming in the shallow waters of WaterSound Beach, one of America's most beautiful white sand beaches, 30 miles south of Destin, Florida. A shark, no one knows what kind, spotted Foley and went on the attack. People on the beach saw what was happening and sprang into action.

The shark clamped its jaws on Foley's arm, then went for her legs.

Among the people already in the water, who immediately rushed to save Foley was Alyssa Huffman.

Huffman was on her first family vacation in three years. She was with her father, who is battling cancer, and this



WaterSound Beach, Florida / Source: Facebook

respite was also time to spend with him. Huffman's children had gone up to the pool with their grandparents.

"While wading in waist-deep water, I heard my sister shouting that she thought a woman nearby might have just been attacked by a shark and that we needed to get out of the water," Huffman told OTW.

"Initially, I dismissed it as kids playing loudly. However, the piercing screams of the victim's children quickly made me realize something was terribly wrong. We rushed over to help pull a woman, whom we later learned was the children's mother, to shore."

Best Care Team Possible

As the shark continued to circle near shore in the blood-filled water, a team including Huffman and multiple doctors, Emergency Medical Services personnel, Emergency Department staff and a Certified Registered Nurse Anesthetist, quickly formed around Foley.

She had lost her left hand in the attack, sustained severe injuries to her pelvic region and was losing blood at an alarming rate.

"As everyone shared their work titles, I recognized the best place for me was

at her head to guide her through what was happening while putting pressure on her brachial artery. The shark had amputated her arm below the elbow,” Huffman said.

“We all knew stopping further blood loss would be critical to her survival and it would take time for EMS to arrive.”

Dr. Toy wasn't on the beach when Foley was initially pulled from the water, but he arrived soon after to help.

He had been at the beach earlier with his family just 150 yards away from where Foley was bitten but had gone back to the house where his family was staying which was not far off the beach.

“My daughter who is 22 called me to let me know a woman had been attacked

so I headed right back to the beach,” he explained. When he arrived, he saw that Foley had been carried to the boardwalk and five or six people were trying to stabilize her, using whatever materials they could find create tourniquets.

Dr. Toy immediately went into lifesaving mode, asking what was injured and trying to get an overall feel for the situation. He said it brought him back to his experiences as a second-year resident when he treated a lot of trauma patients. “She had injuries to the left upper extremity and the pelvic region. We were all focused on keeping her from bleeding out and minimizing the risk of infection.”

Huffman added, “We focused on what we could control...showing her chil-

dren her strength through prayer and breath work while the care team focused on keeping her body functioning. Her husband mentioned she was a marathon runner, so she understood the goal. We practiced breathing slowly—four seconds in, four seconds out—between recitations of the *Serenity Prayer*.”

Huffman said there was no doubt that Foley was a fighter. It took about 30 to 40 minutes for the EMS to arrive because of various access barriers and it was another 15-minute ride to Life Flight where she was immediately operated on.

Divine Intervention

Both Dr. Toy and Huffman believe that strong forces were at play in ensuring

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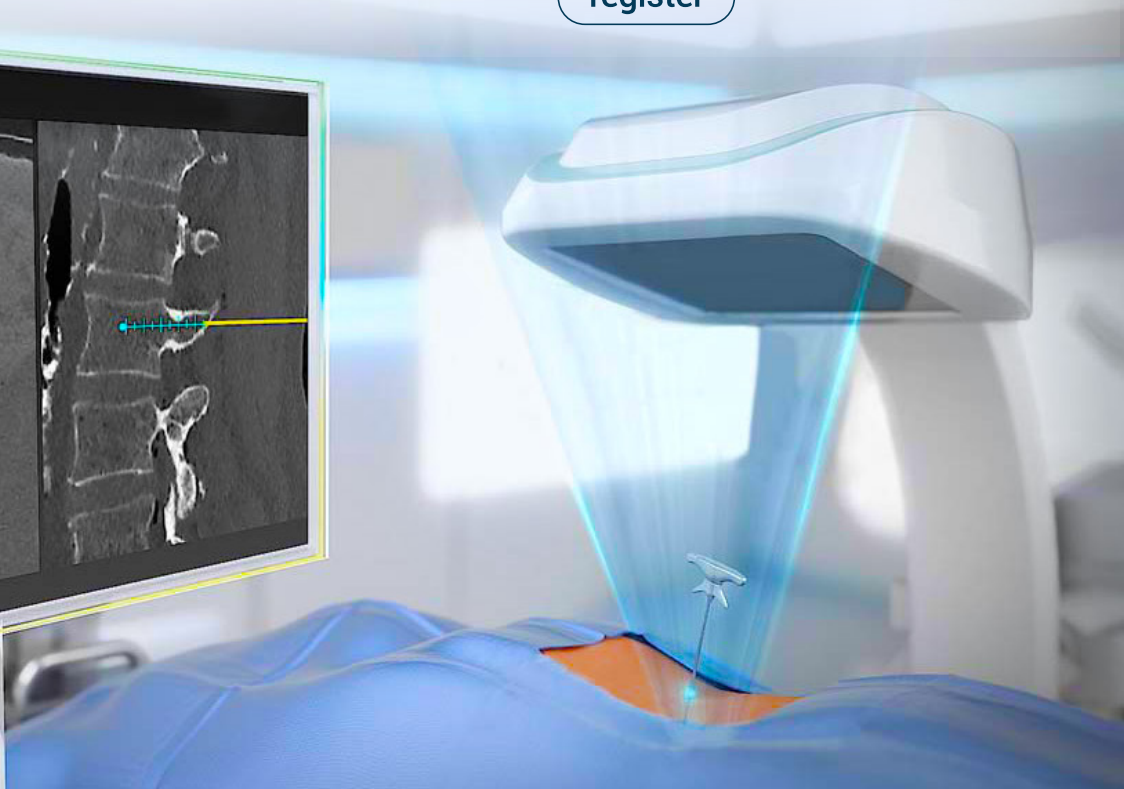
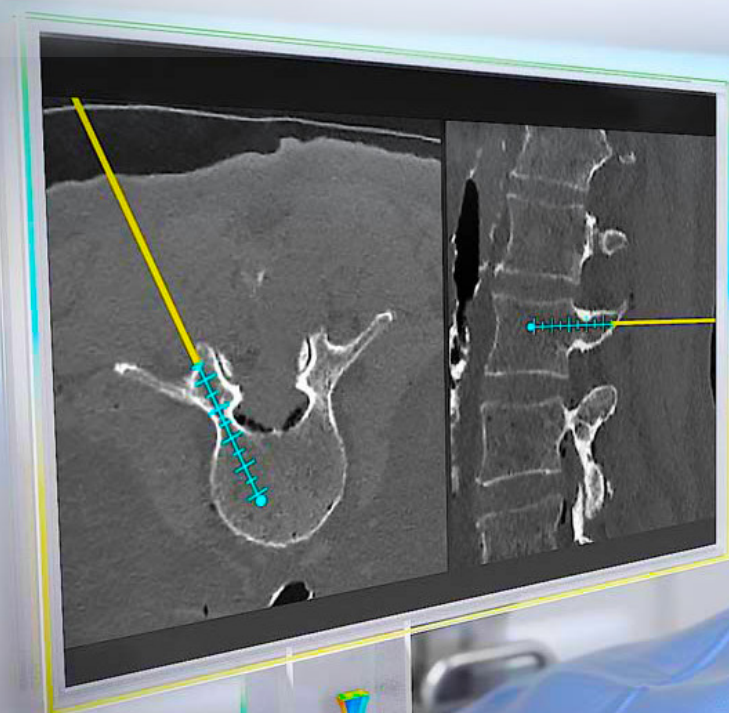
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that Foley had the best care team possible ready to assemble at the beach that day.

Dr. Toy said that while he had never treated a shark attack victim before, the possibility of such an attack had been on his mind after learning about a recent attack that had occurred in California.

“Just an hour before the attack, I remember being in the water with my daughters thinking about the need to be on the lookout for any sharks in the water. What were the odds that an attack would actually happen? It is like being struck by lightning.”

Huffman said, “I reassured [Foley] that divine intervention was at play,

as we had multiple doctors, Emergency Medical Services personnel, Emergency Department staff, and a Certified Registered Nurse Anesthetist attending to her. She was in the best possible hands.”

Foley’s own faith and her church community have also played an important role in her continual recovery.

Dr. Toy has kept tabs on her road to recovery through his former assistant who reached out to close family and friends.

“She is making progress and has good support from her church, family and friends,” he said. Huffman has stayed in touch with Foley and her family through group text. “She will require

many more surgeries, but her medical team was able to salvage her leg which was a major concern due to being attacked in the pelvic region. The kids and her husband were traumatized from the event, and they are all on the long road of healing mentally and physically.”

The entire community of orthopedic suppliers and surgeons have a long tradition of care giving in every way and location imaginable, at home, as volunteers in remote corners of the globe, serving during wartime, as first responders and, even when they least expect to receive the call, on one of Florida’s pristine gulf coast beaches. Thank you, Alyssa Huffman and Dr. Patrick Toy! ♦

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The Smartest Guys in Spine Are Buying ATEC Stock

BY ROBIN YOUNG

Two of the most successful CEOs in the history of spine surgery, Keith Valentine, former CEO SeaSpine and NuVasive, Inc, and David Demski, former CEO of Globus Medical, have both stepped up and bought more shares of Alphatec Holdings, Inc. (ATEC).

Both men are also members of the Board of Directors of ATEC. Indeed, Valentine plus Demski plus ATEC CEO Pat Miles represent the spine industry's version of a Dream Team. Between the three of them, they have built organizations that, this year, will likely sell more than \$2 billion of spinal implants, instruments and biologics.

Keith Valentine bought 39,000 ATEC shares and David Demski bought 40,000 ATEC shares.

Alphatec's stock has been under severe pressure since July 31 when the company reported that \$0.29 per share loss for the June 2024 quarter, which was 3 pennies less than the consensus Wall Street estimate of \$0.26. The \$0.29 loss per share was a substantial improvement from last year's \$0.43 per share loss for the same period.

Sales came in at \$146 million, up an industry leading 27%. For the fifth year in a row, Alphatec is the #1 market share gainer in spine. Those sales figures beat Wall Street's expectations and CEO Miles raised his sales guidance for the rest of 2024.

It's been no secret that ATEC has been under pressure to report profit. And Wall Street punished the company by



Source: Wikimedia Commons

pushing ATEC's price from \$10.45 on July 31 to \$6.10 as we write this article.

A Time-Tested Wall Street Strategy for Making Money

No surprise to most people, I suppose, but Wall Street is emotional and volatile. The real investment pros love when Wall Street either over buys or over sells. The key to the greatest returns comes from understanding underlying economic trends and taking advantage of emotional selling or buying.

It is, therefore, instructive that two of the most savvy and, importantly, board members (and, therefore, insiders) at

ATEC are buying more stock.

At current prices, Alphatec Spine is worth \$858 million. In four years, ATEC's sales have soared from \$145 million to \$540 million (trailing 12 months). ATEC has been gobbling up market share at a faster rate than any other spine company since Pat Miles and his team have taken over.

At the current valuation, ATEC is very cheap. How cheap? Price to sales is 1.62. The average for a spine or orthopedic company is 4.05x.

And the smartest guys in spine are buying more ATEC stock. ♦

COMPANY

Globus Sales Hit \$630 Million, up 116%

At this rate, Globus Medical, Inc. will likely reach \$2.5 billion in total revenue for the 12 months ending December 31, 2024...and earn around \$250 million in operating profits.

Of course, these numbers include the results of the September 1, 2023, acquisition of NuVasive, Inc.

Here's the tale of the tape: (See table on page 13.)

Six Months Combined

The Globus and NuVasive field teams have now been combined for six months and, so far, so good. The profit



Courtesy of Globus Medical, Inc.

rate is not as high as CEO Dan Scavilla or CFO Keith Pfeil would like: "Free cash flow was \$26 million for the quarter, and adjusted EBITDA decreased 30% as we build our way back to the mid-30s range," said Scavilla on his call with analysts.

But, the teams have been able to move four new products through channels in the June 2024 quarter and deliver essentially \$630 million in sales. So far in 2024, Globus has rolled out nine new products. If management keeps the pace up,

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total new launches in 2024 could hit a record.

Top performing product categories were expendables, biologics, MIS screws, and the Simplify Cervical Disc.

What to Expect at NASS’s September 25th Annual Meeting

Globus’s key launches this year, which will almost certainly be featured at their booth at NASS are:

- The Revel-S is an expandable stand-alone ACDF spacer system
- HILINE is a versatile posterior band fixation system for the cervical and thoracolumbar spine
- The XLIF prone system
- AUTOBAHN Pro instruments and Digital Targeting System

Finally, Globus reported that their total joint arthroplasty product line received five new FDA 10-k clearances in the first six months of 2024. Most notably, is the clearance for the Excelsius Flex robotic navigation platform which is intended to pair with Globus’s ExcelsiusFlex TKA, a total knee arthroplasty system.

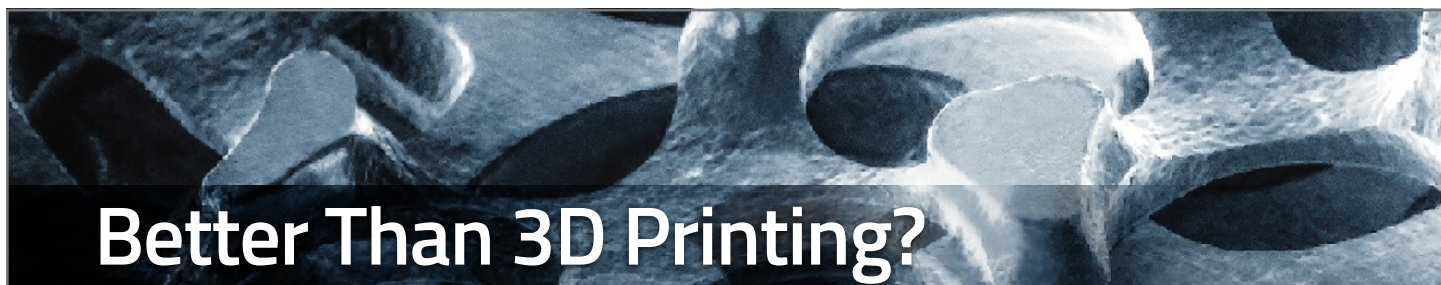
Wall Street’s Take

Wall Street summarized Globus’s June performance in four words; “Not Missing a Beat.” Wells Fargo’s analyst, Vic Chopra, upgraded his opinion to “Overweight.” — RRY

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(In thousands, except per share amounts)	2024	2023	2024	2023
Net sales	\$ 629,691	\$ 291,615	\$1,236,357	\$568,303
Cost of sales	260,040	76,473	501,527	147,298
Gross profit	369,651	215,142	734,830	421,005

Courtesy of Globus Medical, Inc.



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Bioventus Sales up 14%, Cash up 40%

The most arresting statistic in Bioventus's June 2024 quarter report was cash from operations—up a whopping 40.5% to \$15.2 million. The June report shows that, under new CEO Rob Claypoole, Bioventus has bounced back smartly from its dark days of just 13 months ago, when the company had to shed assets just to keep itself solvent.

Total non-organic sales for the June quarter were \$134 million, up a respectable 10.3%.

In what appears to be near record time, Claypoole and his team are reporting that organic sales (that doesn't mean pesticide-free, it means actual sales of actual goods, ignoring currency fluctuations) grew 13.9%.



Courtesy of Bioventus, Inc.

There were two big product category winners in the quarter: Pain Treatments, up 17.2% and Surgical Solutions, up 18.6%.

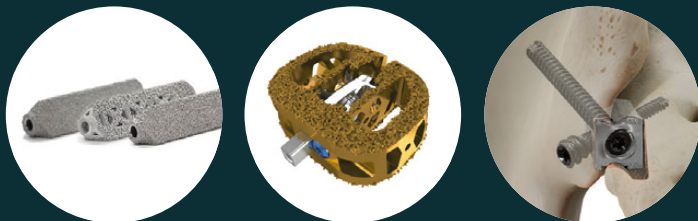
Pain treatments are Bioventus's largest business, accounting for \$65.2 million in sales for the June quarter or 49% of total sales. Number 2 is Surgical Solutions at

\$41.8 million or 31% of total sales. And bringing up the rear is Restorative Therapies at \$27 million, down 8.6%.

One year ago, investors could have snapped up shares of Bioventus for just \$2.92. Today it will cost an investor \$7.54 to buy that same share. That's 2.5x the return in one year. — RRY



HOW IS SI JOINT TREATMENT CHANGING?



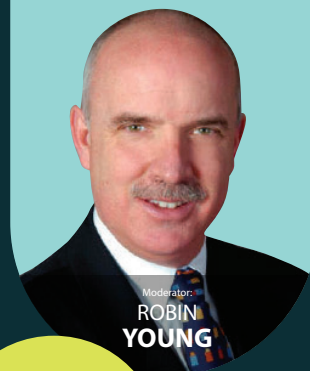
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Centinel Spine Reports Record prodisc Sales for Q2

Disc arthroplasty pioneer and market leader, West Chester, Pennsylvania-based Centinel Spine announced that sales for the June quarter of 2024, not only set a record, but grew 26% year-over-year.

Driving the sales growth was, of course, the ever-expanding prodisc® portfolio of total disc replacement products and associated procedure instrumentation. To be clear, Centinel Spine, the market leader in total disc replacement products, not only set a sales record, but also outperformed its previous record quarter—which was Q1 of 2024!

For the quarter ending June 30, 2024, Centinel Spine reported \$22.1 million



prodisc® portfolio / Source: Centinel Spine®, LLC

in worldwide prodisc total disc replacement revenue, representing a 26% year-over-year growth. The company also announced that worldwide prodisc cervical revenue grew 32% year-over-year to reach \$14.6 million. U.S. sales for prodisc cervical disc rose 42% year-over-year growth.

Revenue was not the only area of growth, Centinel Spine also expe-

rienced an increase in surgeon use. Notable, per the press release, “record U.S. prodisc total surgeon user-base of nearly 600 surgeons, representing almost 40% YOY growth and sequential quarterly user growth of 10%.” This was the eighth consecutive quarter of surgeon user growth for the company.

Centinel Spine CEO Steve Murray commented, “The second quarter rep-

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resents another record performance for Centinel Spine and these results demonstrate the continued strength behind our prodisc cervical and lumbar business in the rapidly expanding Total Disc Replacement market, worldwide.”

Murray continued, “The prodisc portfolio leads the Total Disc Replacement market in growth and has a long history of reliability and long-term performance. The new prodisc C Vivo and prodisc C SK Cervical System continues to excel, as exhibited by a rapidly expanding user base, record new users for the quarter, and strong repeat usage performance.”

In the third quarter 2022, the New Match-the-Disc™ prodisc C Vivo and prodisc C SK Cervical System had a limited U.S. release. Since that time, almost 7,000 procedures have been performed with the new system. Additionally, the company wrote “record prodisc C Vivo and prodisc C SK revenue in Q2 2024, representing nearly 67% and 100% YOY growth, respectively.”

In the second quarter of this year, according to the company, the number of surgeons using prodisc increased “nearly 140% YOY and almost 20% in sequential quarterly growth.” — KD

Patient Compliance App Receives MedTech Breakthrough Award

Lewisville, Texas-based Orthofix Medical Inc. has won the “Best Patient Experience Solution” award in the 2024 MedTech Breakthrough Awards program.

Orthofix was recognized for its STIM onTrack™ mobile app. After a fracture injury, lumbar fusion, or cervical fusion, the STIM onTrack mobile app can track patient compliance data. The data comes from a prescribed bone growth therapy device.

Jason Shallenberger, president of bone growth therapies at Orthofix, told OTW: “We are extremely honored to be recognized for the second year in a row as a winner of the Medtech Awards—this year for Best Patient Experience Solution.”

Shallenberger continued, “Orthofix was the first company in this space to recognize the importance of patient engagement in their own recovery by utilizing our STIM onTrack app. This allows patients to report a variety of information back to their physician such as pain scores and treatment compliance among other things.”

According to the company, the mobile app “provides a hyper-targeted experience that addresses unique patient needs related to bone healing.” It works with the “latest generation CervicalStim™, SpinalStim™, and PhysioStim™ bone growth therapy devices.”

App features dedicated to helping patients maintain their treatment schedules include treatment reminders and device usage calendars. Patients are also able to use the app to transmit important data to their physi-

cians to help with remote patient monitoring. Patients can also access links to educational resources through the app.

MedTech Breakthrough is part of Tech Breakthrough, a market intelligence organization. The MedTech Breakthrough Awards program is an annual program that, per its website, “recognizes the ‘BREAK THROUGH’ companies, people, platforms and products in the health, fitness and medical technology industries today.” It covers a range of categories including the following: clinical and health administration; patient engagement; electronic health records; internet-of-things (IoT) healthcare; medical data; health and fitness; mobile communications and telehealth; medical device; healthcare cybersecurity; and industry leadership.

This year is the eighth year of the awards program. Thousands of nominations were submitted to the program from more than 18 different countries. — KD



STIM onTrack™ mobile app tracks patient compliance data from their bone growth therapy device which is prescribed after a fracture injury, lumbar or cervical fusion / Source: Orthofix Medical Inc. and Business Wire

LEGAL

FDA Clears Camber Spine's New Anterior Integrated System

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to a new, integrated, lumbar (3D printed) interbody fusion system for anterior spine surgery indications.

According to the FDA's 510(k) summary document, this new device, brand-named SPIRA-A anterior lumbar spacer is cleared for commercialization and "indicated for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease

(DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis and failed previous fusion (pseudarthrosis)."

Additionally, the SPIRA-A is "intended to be used with additional FDA-cleared

supplemental fixation systems." Furthermore, the spacers system "must be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft."

Furthermore, SPIRA-A is also indicated for "one or more levels from L1-S1 as an



SPIRA-A Integrated Fixation System / Source: Camber Spine Technologies



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adjunct to fusion in skeletally mature patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy) spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis and failed previous fusion (pseudarthrosis).” The integrated fixation system spacers “must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.”

Camber Spine Technologies, based in King of Prussia, Pennsylvania, is the manufacturer and will be featuring the new Camber SPIRA® Anterior Lumbar Spacers at the upcoming North American Spine Society annual meeting.

Camber Spine CEO Brooks McAdam said, “The FDA’s 510(k) clearance of our SPIRA-A Integrated technology ushers in the next evolution in our innovative SPIRA platform and marks another major step forward in our company’s development.”

McAdam continued, “It also helps bring more innovation-based solutions and options to the surgical community and a solution for surgeons engaging or wanting to engage in the ALIF market. We believe SPIRA Technology, which encompasses the structure, surface, and science behind our 3D-printing process, is the archetypal design for modern spine implants and exemplifies the true benefits of additive manufacturing.”

Camber Spine’s SPIRA implants are 3D printed, which, according to Camber, “creates unique patented structures featuring open arched matrices and proprietary surfaces designed to enhance fusion and promote bone growth.”

A device must be substantially equivalent to a predicate device to qualify for shorter and earlier 510(k) clearance. According to the 510(k) summary document the anterior lumbar spacers are substantially equivalent to the following primary predicate device by Camber Spine Technologies: SPIRA® Open Matrix ALIF. Also per the 510(k) summary document, the integrated fixation system is “most similar in design and indications for use to the predicate Globus Medical HEDRON IA and CORBEL spacers.” — KD



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Nine NEW Shoulder Arthroplasty Patents Issued

The United States Patent and Trademark Office (USPTO) has recently granted nine patents to Shoulder Innovations, Inc., a Grand Rapids, Michigan based emerging shoulder arthroplasty growth company.

The patents, which were granted over the last 18 months, teach “less invasive surgical techniques” for a range of shoulder replacement surgeries and indications.

The patents are: US-12023254-B1 and US-11771561-B2 for total reverse shoulder systems and methods; US-11992415-B2 and US-11957595-B2 for methods and devices for less invasive glenoid replacement; US-11696772-B2 for methods for less invasive glenoid replacement; and US-D977643-S for humeral stem implant.

According to the Shoulder Innovations, the patent for the total reverse shoulder systems and methods features a “reverse shoulder system with a scapular glenoid baseplate and humeral stem, where the baseplate's axis is angled relative to the stem's axis.”

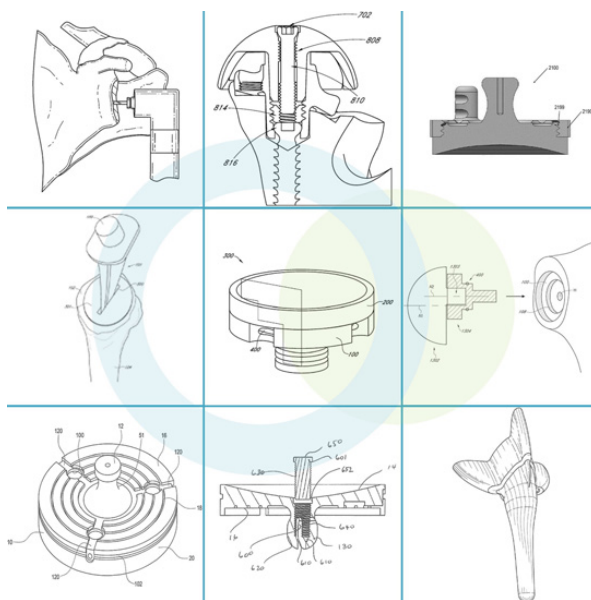
The patent for glenoid preparation in a single step involves a “ground-breaking method of implanting a glenoid implant, which involves reaming two cavities in the glenoid in a single step.”

The porous coated convertible glenoid patent is comprised of “shoulder replacement components and methods utilizing porous fixation rings, enabling the switch from anatomic to reverse articulating surfaces without changing the fixation components.”

Much of the company's focus has been on developing systems and solutions to address glenoid loosening.

Shoulder Innovations CEO Rob Ball commented, “These recent grants further strengthen key patent families that are foundational to our technology, and we are pleased the USPTO continues to recognize our meaningful innovation in the shoulder arthroplasty segment.”

Ball continued, “This noteworthy expansion of our IP position represents the culmination of over 10 years of research and development, and we are proud of our team for their continued dedication to creating practical solutions for shoulder surgeons and advancing patient outcomes.” — KD



Shoulder Innovations' Patents / Source: Shoulder Innovations, Inc.

Is SpineFrontier's Legal Saga Settled?

According to court documents, a settlement has been reached between the United States government and the parties involved in a case alleging the payment of kickbacks to spine surgeons.



Source: Pixabay and AJEL

The settlement includes those civil claims filed by the relators in the matter as well as by the United States government. In a False Claims Act case the relator is a private party who files the action on behalf of the United States and can receive a portion of the recovery.

Here, the claims alleging illegal kickbacks included the following parties listed as defendants: SpineFrontier, Inc.; KIC Ventures, LLC; KIC Management Group, Inc.; Impartial Medical Experts, LLC; AxioMed, LLC; Kingsley R. Chin, M.D.; Aditya Humad; and Vanessa Dudley.

Earlier this year, the United States and relators entered into a stipulation to partial dismissal with all of the parties. The relators dismissed their claims with

prejudice (permanently) and the United States dismissed its claims without prejudice.

The relators reserved a number of claims including their claims for reasonable expenses, attorneys' fees, and costs and relief from retaliatory actions. In a successful action, a relator may be entitled to a portion of the recovery. Here, the relators, per court documents, did not "waive any claim to a share of the settlements that the United States entered into with certain physicians and surgeons, nor does the United States waive any of its defenses thereto."

It also appears from court documents that the relators are entitled to an award from the government's recoveries from six of the surgeons settling allegations related to the kickbacks. This was ordered by the court in June after the

United States opposed the relators' claims for recovery.

The settlements resolved all of the claims except a retaliation claim brought by one of the relators and fee and payment amounts. The discovery proceedings in the retaliation proceedings were stayed pending the criminal proceedings in the matter. The criminal proceedings have a jury trial date set for October 7, 2024 and include Dr. Chin, Humad, and SpineFrontier.

For OTW's previous coverage of the ongoing litigation, see "[Indictment Charges SpineFrontier Owner in Alleged Kickback Scheme](#)," "[Missouri Surgeon and Kansas Distributor Plead Guilty To Kickbacks](#)," "[Surgeon Pays \\$1.75 Million To Settle Kickback Allegations](#)," and "[U.S. Attorney Sues SpineFrontier Over Alleged Kickback Scheme](#)." — KD

Medicare Death by a Thousand Payment Cuts? AMA Pushes Back!

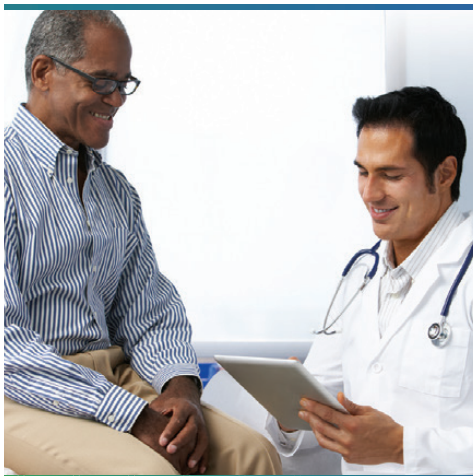
For the fifth consecutive year, the Centers for Medicare and Medicaid Services (CMS) is threatening to cut payments, this time by 2.8%.



Source: Shutterstock

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Unacceptable, says the American Medical Association (AMA).

And the AMA is taking this fight to Congress.

According to AMA President Bruce A. Scott, M.D., this is death by a thousand cuts. Five years of cut, cut, and more cuts.

A recent statement issued directly by CMS stated that the cuts were closer to 2.93%. Furthermore, said Dr. Scott, “CMS predicts the Medicare Economic Index (MEI)—the measure of practice cost inflation—will increase by 3.6%.”

With the gap between Medicare’s reimbursement to physician for services and the cost of delivering care to patients growing, the AMA is urging Congress

to pass H.R. 2474. “The Strengthening Medicare for Patients and Providers Act [is] a bipartisan bill that would provide a permanent, annual update equal to the increase in the Medicare Economic Index,” Dr. Scott said.

“Additionally, the AMA has a proposal to make Merit-based Incentive Payment System (MIPS) more relevant to patients and supports pending legislation to improve the budget neutrality process to better reflect actual Medicare costs.”

According to Dr. Scott, adjusted for inflation, Medicare physician payment has declined by 29% from 2001 to 2024. For many physicians, this has resulted in the inability to absorb rising costs. Moreover, the Medicare

Physician Payment Advisory Commission and the Medicare Trustees have warned against the dangers of repeated cuts to Medicare payments, including the harmful impact on patient access to care.

For now, Dr. Scott says, “The death by a thousand cuts continues. Rural physicians and those treating underserved populations see this CMS warning as another reminder of the painful challenges they face in keeping their practices open and providing care.”

Previous quick fixes to address this issue have been insufficient and “a bold, substantial approach” is needed, the AMA president said. “A Band-Aid only goes so far when the patient is in dire need.” — NN



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PEOPLE

Kris Alden, M.D., Ph.D., Joins The Steadman Clinic

Kris Alden, M.D., Ph.D. a highly experienced orthopedic surgeon, has joined the surgical team at The Steadman Clinic in Colorado. Formerly based in Florida, Dr. Alden, brings his expertise in hip and knee care, including extensive experience in joint replacement surgery as well as non-surgical treatment of hip and knee arthritis and related disorders.

With a background in biophysics—he earned his Ph.D. in the field, alongside his M.D. at the University of Illinois—Dr. Alden has a strong interest in the



Kris Alden, M.D., Ph.D.
Courtesy of The Steadman Clinic

use of innovative surgical techniques. “Patient-specific instrumentation, [for example] is a mechanism that [allows us to] customize the total knee to fit each patient individually and adjust

for their sizes, anatomic, dimensions and deformity so we can correct it in an optimal way.” He has also been a leader in establishing clinical care pathways and protocols to allow minimally invasive joint replacement surgery in the outpatient setting, with the goal of achieving a more rapid recovery and return to mobility with fewer complications.

After earning his M.D./Ph.D., subsequent training at The Johns Hopkins Hospital and at the Mayo Clinic cemented Dr. Alden’s interest in hip and knee replacement, minimally invasive surgery, and complex revision surgeries. Many years of practice in the Chicago area followed, where he had earned his undergraduate at the University of Chicago.

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prompted Dr. Alden's decision to join The Steadman Clinic. "When I first talked to the physicians at Steadman, I was extremely impressed with not only the clinical expertise of the group, but also their overall dedication to outstanding patient care," Dr. Alden said.

In turn, Marc Philippon, M.D., managing partner of The Steadman Clinic and chair of the Steadman Philippon Research Institute, saw Dr. Alden's surgical expertise and patient philosophy as an excellent match for The

Steadman Clinic. "Bringing an outstanding hip and knee specialist such as Dr. Alden into our roster continues to strengthen our surgical team," Dr. Philippon said.

Dr. Alden cares for patients at the Steadman Center's clinics in Aspen Valley and Basalt, Colorado. In a setting often associated with skiing and other athletic pursuits, he sees a range of injuries and conditions, including patients who have developed pain and debility owing to a sedentary lifestyle. For this popula-

tion, surgery can also make a dramatic difference. "I love what we are able to accomplish with hip and knee replacement procedures because that enables people to become more active and get back to doing the activities that they enjoy, which is what life is all about," Dr. Alden said.

"Having access to a world-class research facility is just a phenomenal part of the position at The Steadman Clinic and I'm thrilled to be a part of it," he added.
— NN



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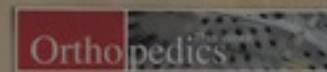
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