

# Orthopedics This Week

## WEEK IN REVIEW

**4 Are Your Sterile Implants Really Sterile? >>** Even reprocessed pedicle screws may be contaminated. It's a very serious issue. A group of leading researchers are proposing improved standards for handling and delivering pedicle screw implants to reduce and possibly eliminate contamination and therefore the risk of deep bone spine surgical site infection.

**9 Orthopedic Practice Consolidation Jumps 45% in 2018 >>** In the first six months of 2018, 94 physician groups have sold or merged their practices, that's up 45% from the record setting pace in 2017. What's going on? Jeff Swearingen, co-founder and managing director of New York City-based private equity firm Edgemont Capital explains.

**13 Gehrke v. Sculco: Routine Use of Antibiotic Bone Cement in Primary TJA is Justified >>** Periprosthetic joint infection is a catastrophic problem but is avoiding catastrophe reason enough to justify routine use of antibiotic bone cement? This debate tackles both that issue and differences between U.S. and European approaches. Very informative.





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**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Time for Q3 sales and earnings report cards. Big news—NuVasive's CEO Lucier steps away from day-to-day duties and hands the reins to Medtronic's former head of surgical innovations, Chris Barry. Investors respond by dropping NUVA's price 9%. They're worried that NUVA has bad Q3 new. NUVA is OK. Investors see goblins and ghosts around every corner. Plus, good news from China. Central Committee cuts taxes. Boosts money supply. Who said communists can't act like capitalists?

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Johnson & Johnson	24.44%	(1.00%)	Back to #1 on the Power Rankings on the strength of a Q3 DePuy Synthes reported sales growth rates that beat Wall Street's very, very modest expectations.
2	5	Integra LifeSciences	16.97	(0.62)	The purchase of Codman from DePuy has really skewed the sales and earnings numbers—in a good way. For Q3 Wall Street is looking for more than 30% pop in sales.
3	1	Medtronic	22.84	(2.61)	Really stellar NASS, one of MDT's best. The purchase of Mazor, integration of stealth station with robotic assistance and instruments keeps momentum going.
4	4	Orthofix	8.77	6.29	OFIX is the ONLY ortho company in the Power Rankings whose value is up over the past month.
5	3	Stryker	22.01	(2.65)	26 analysts cover SYK and in their collective wisdom, believe that SYK will post a sales growth rate of 8% year over year—or better—for Q3.
6	6	Zimmer Biomet	20.8	(4.19)	Barclays initiated coverage on ZBH last week with an "underweight" opinion. Yes, sales growth rate is 1% or less. But cash flows and market share remain excellent.
7	7	Smith & Nephew	17.31	(9.83)	For Q2, SNN reported 2% organic growth (3% reported sales growth). Under new CEO Nawana, will SNN find ways to get old SNN to pick up the pace?
8	9	Alphatec Holdings	(16.86)	(5.15)	CEO Miles is assembling a notably strong sales, marketing and product development team. 2018 is transition. 2019 and beyond is execution.
9	10	ConMed	8.97	(8.91)	For Q3 most analysts covering CNMD expect CEO Hartman and his team to grow the business roughly 4% over last year's levels.
10	NR	NuVasive	10.67	(11.40)	NUVA lost more than 11% of its value in the last month. It is now in bargain territory and, therefore, a prime candidate for the Power Rankings.

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Amedica Corp	AMDA	\$0.33	\$4	23.74%
2	Aurora Spine	ASG.V	\$0.28	\$11	10.60%
3	SeaSpine Hldgs Corp	SPNE	\$16.50	\$297	8.20%
4	Orthofix	OFIX	\$56.77	\$1,074	6.29%
5	RTI Surgical	RTIX	\$4.57	\$290	5.06%
6	K2M Group Hldgs	KTWO	\$27.35	\$1,196	0.29%
7	Globus Medical	GMED	\$52.54	\$5,162	0.21%
8	Lattice Biologics	LBL.V	\$0.02	\$2	-0.09%
9	Integra LifeSciences	IART	\$62.58	\$5,328	-0.62%
10	Johnson & Johnson	JNJ	\$139.05	\$373,037	-1.00%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Xtant Medical Hldgs	XTNT	\$3.25	\$43	-27.94%
2	Nevro Corp	NVRO	\$50.30	\$1,515	-13.99%
3	MicroPort Scientific	853	\$1.18	\$1,735	-13.46%
4	NuVasive	NUVA	\$62.05	\$3,191	-11.40%
5	Dynatronics Corp	DYNT	\$2.93	\$24	-9.85%
6	Smith & Nephew	SNN	\$33.40	\$14,603	-9.83%
7	ConMed	CNMD	\$71.74	\$2,017	-8.91%
8	Pacira	PCRX	\$47.00	\$1,925	-8.47%
9	AxoGen	AXGN	\$33.51	\$1,284	-6.66%
10	Alphatec Holdings	ATEC	\$3.13	\$133	-5.15%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Smith & Nephew	SNN	\$33.40	\$14,603	19.04
2	Johnson & Johnson	JNJ	\$139.05	\$373,037	21.17
3	Zimmer Biomet	ZBH	\$124.40	\$25,314	23.69
4	Medtronic	MDT	\$93.94	\$126,867	25.13
5	MiMedx Group	MDXG	\$5.31	\$590	26.89

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	\$31.99	\$1,176	124.47
2	MicroPort Scientific	853	\$1.18	\$1,735	92.20
3	RTI Surgical	RTIX	\$4.57	\$290	82.19
4	NuVasive	NUVA	\$62.05	\$3,191	63.01
5	Orthofix	OFIX	\$56.77	\$1,074	59.21

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MicroPort Scientific	853	\$1.18	\$1,735	1.58
2	MiMedx Group	MDXG	\$5.31	\$590	1.79
3	Integra LifeSciences	IART	\$62.58	\$5,328	2.59
4	Stryker	SYK	\$168.94	\$63,182	2.72
5	Johnson & Johnson	JNJ	\$139.05	\$373,037	2.72

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$56.77	\$1,074	6.30
2	RTI Surgical	RTIX	\$4.57	\$290	5.48
3	Zimmer Biomet	ZBH	\$124.40	\$25,314	5.29
4	Smith & Nephew	SNN	\$33.40	\$14,603	5.01
5	CryoLife	CRY	\$31.99	\$1,176	4.15

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Amedica Corp	AMDA	\$0.33	\$4	0.35
2	Dynatronics Corp	DYNT	\$2.93	\$24	0.37
3	Xtant Medical Hldgs	XTNT	\$3.25	\$43	0.52
4	Lattice Biologics	LBL.V	\$0.02	\$2	0.59
5	RTI Surgical	RTIX	\$4.57	\$290	1.04

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Flexion Therapeutics	FLXN	\$18.94	\$716	2017.54
2	AxoGen	AXGN	\$33.51	\$1,284	21.25
3	Globus Medical	GMED	\$52.54	\$5,162	8.12
4	Pacira	PCRX	\$47.00	\$1,925	6.72
5	CryoLife	CRY	\$31.99	\$1,176	6.20

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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# Are Your Sterile Implants Really Sterile?

BY KIM DELMONICO

**C**ontaminated pedicle screws are a huge problem in the United States. They cause increased surgical site infections (SSI), causing increased hospitalizations and costing hundreds of thousands of dollars every year. A multicenter group of researchers has proposed a superior standard of care and method of delivery for pedicle screws that completely eliminates this contamination.

## 12.7% Incidence Rate of Surgical Site Infection

A 2016 study published in the *International Journal of Spine Surgery* found that surgical site infection occurs at the rate of 12.7% following spinal fusion surgery. The average hospital bill following such infections is \$63,000, with hospitalization being necessary in 5.5% of those cases.

Pedicle screws are the most common implant used in spinal fusion surgery. A surgeon will typically have over a hundred screws available for use during surgery, but actually use a very small number of them.

The pedicle screws' low usage rate leads to these screws being repeatedly reprocessed—or “automated washing with contaminated instruments from theatre and then sterilized without prior inspection by hospital staff” by the sterilization processing department (SPD).

These “sterile” implants, alarmingly, have been found to contain contaminants.

Furthermore, unused pedicle screws are subject to contamination during surgery.



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## Reprocessing Contamination

Reprocessed pedicle screws have been shown in recent studies to harbor contaminants, even after the automated washing and sterilization process.

One such study by Aakash Agarwal, Ph.D. and colleagues published in the *Global Spine Journal*, “[Harboring Contaminants in Repeatedly Reprocessed Pedicle Screws](#),” found evidence of corrosion, saccharide, and soap residue on a random selection of pedicle screws that were supposedly sterile and consigned to be used during surgery.

In their study, the researchers selected six pedicle screws from four different trays of cleaned, wrapped, and sterilized implants. The screws were disassembled and sent for optical microscopy, scanning electron microscopy, and Fourier transform infrared spec-

troscopy. The researchers also reviewed the four major manufacturer’s instructions for reprocessing pedicle screws and compared the steps to the actual procedures that sterilization processing departments (SPDs) used to reprocess a pedicle screw set.

The study found three different types of contaminants on the sterilized pedicles screws: corrosion, saccharide of unknown origin, and soap residue. The study also found that manufacturer’s guidelines recommended 19 hours equivalent of reprocessing, but actual turnaround time was only 1 hour and 17 minutes.

The exact origin of these contaminants is unknown but could range from mucous-like deposits from bacteria, biofilms, fatty tissue residues from reprocessing the implants with other contaminated instruments, and insufficient rinsing after cleansing.

This could be in part due to the fact that pedicle screws are multicomponent with lumens, interfaces, and crevices that range from 0.2 to 1.5mm. These results raise important concerns regarding the practicality and safety of a repeated cleaning and sterilization process being followed in most of the hospitals in United States.

### More Issues With Reprocessing Implants

Previous studies have also concluded that reprocessing in health facilities is impractical given the workload and the intricacies of the devices.

Earlier studies have shown that reprocessing led to an increase in endotoxin levels on implants and instruments. The study by Alfa et al. concluded that the final deionized (DI) water rinse was the source of the contamination,

noting that there was biofilm formation in the DI tank.

Scotland has completely banned reprocessing of implants that are used in spine surgery. In Scotland, the deadline for conversion of orthopedic units to prepackaged, sterile, single-use implants was December 31, 2007. We are approaching 2019, and United States still has not mandated such changes, while other countries like the Netherlands and Japan are actively enrolling or approaching uniformity in this new practice.

The researchers concluded that repeatedly reprocessing pedicle screws could be a cause of surgical site infection and inflammatory responses post-surgery and suggested that the use of prepackaged, sterile, single-use implants as the only alternative.

### Intraoperative Contamination

Reprocessing is not the only source of contamination for pedicle screws. Screws that are initially sterile are also contaminated during surgery.

In a separate study published by Agarwal and team in the *Global Spine Journal*, "[Implant Prophylaxis: The Next Best Practice Toward Asepsis in Spine Surgery](#)," the researchers analyzed articles published between 2000 and 2017 that evaluated the contaminants present on spine implants and the associated processing and handling methodology suggested to avoid them.

In conducting their study, the researchers asked: "What are the sources of contaminants on an implant used for surgery?" and "What are the known practices and/or suggested implant handling techniques, both preoperative and intra-

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operative?” Eleven articles were found that were relevant for the analysis.

Five of the 11 articles showed that surgical gloves were a vehicle for contamination. One study showed that changing gloves just prior to handling a pedicle screw could reduce infection rate from 3.35% to 0.48%. This study concluded that avoiding the transfer of patient’s skin flora to the implant (and subsequently deep in the bone) via surgical gloves reduced infection.

Exposure was shown to cause implant contamination in 3 out of the 11 articles. In one of these studies, researchers covered implants immediately after opening and compared them to a sample of uncovered implants. Only 2.0% of the covered implants demonstrated contamination compared to a 16.7% rate of contamination for the uncovered implants. Another group of researchers who compared the differences in

contamination between covered and uncovered implants found that the after 120 minutes of exposure, the covered group of implants were 18.2% contaminated, while the uncovered implants were 55% contaminated.

Based on these studies, Agarwal and colleagues concluded that the current techniques for handling and processing implants were in need of scrutiny and called for new policies and procedures for handling sterile implants.

### Two-Part Solution

The problem with pedicle screw contamination is twofold—first, contamination through reprocessing and second, contamination in the operating room, i.e., inside ‘sterile’ field.

The problem of contamination through reprocessing can be solved by using single-use, pre-sterilized screws. To com-

bat the issue of intraoperative pedicle screw contamination, Agarwal and colleagues developed the method of intraoperative implant prophylaxis (IIP) that could reduce pedicle-screw led deep-bone surgical site infection and screw loosening (due to biofilm formation between bone and screw).

The researchers published their results in a *Global Spine Journal* article, “[Efficacy of Intraoperative Implant Prophylaxis in Reducing Intraoperative Microbial Contamination](#),” and numerous conference proceedings.

The participating researchers included Boren Lin, Ph.D.; Jeffrey C. Wang, M.D.; Christian Schultz, M.D.; Dean Steve R. Garfin, M.D.; Vijay K. Goel, Ph.D.; Neel Anand, M.D.; Anand K. Agarwal, M.D.; Hossein Elgafy, M.D.; Dennis McGowan, M.D.; Josue P. Gabriel, M.D.; and Chris Karas, M.D. who are associated with University of Toledo

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in Toledo, OH; USC Spine Center in Los Angeles, CA; Apex Spine Center in Munchen, Germany; University of California in San Diego, CA; Spine Institute of Ohio in Hilliard, OH; OhioHealth Grant Medical Center in Columbus, OH; Kearney Regional Medical Center in Kearney, NE; and Cedars Sinai Medical Center in Los Angeles, CA.

To avoid intraoperative contamination, Agarwal and colleagues implemented a method of shielding the pedicle screws intraoperatively using a guard. General surgeons and plastic surgeons already do this, using wound edge protectors and Keller funnels to provide a better barrier against contamination.

In their multicenter studies, the researchers used two groups of pre-packaged, sterile, single-use pedicle screws: the first group had an intra-

operative guard and the second group did not have a guard. Each group consisted of 26 samples that were distributed over 23 time points (independent spinal fusion surgeries). Each was performed in a different operating room by different surgeons and surgical staffs.

During surgery, each of the screws were loaded on insertion devices by the scrub tech and was left on the sterile table. Approximately 20 minutes later, the lead surgeon who had just finished preparing the surgical site checked the pedicle screw for alignment. Then, instead of implantation, the screws were transferred to sterile containers using fresh sterile gloves for bacterial analysis.

Spectrophotometry detected saturated levels of turbidity within 24

hours for the group of screws that did not have a guard. The standard unguarded pedicle screws presented bioburden in the range of  $10^5$  to  $10^7$  (colony forming units/implant). The strains of bacteria that were found on the unguarded screws, included *Staphylococcus epidermis*, *Staphylococcus aureus*, *Micrococcus luteus*, and *Staphylococcus pettenkoferi*. The group of screws that did have a guard showed no turbidity or bacterial growth for the entire 14-day incubation period.

### Significance of the Findings

OTW spoke with Agarwal about his team's findings. He said, "Our research signifies the utmost importance of: 'providing sterile implant to the operating theatre, and then making sure it remains sterile.'"



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Agarwal explained that, “The likelihood of post-operative infection depends on three factors:

- (1) the dose of bacteria left from surgery;
- (2) the virulence of bacteria; and
- (3) the patient’s immune (natural or boosted by antibiotics) response at the surgical site.

Not all patients will have infections, but some will (the latest research shows 12.7% do; but even if 1% did we should still care.)”

“A rate of 10% implies 100,000 people annually just in the U.S. alone. It is in patient’s best interest to be exposed to the least amount of bacterial dose dur-

ing surgery; many of these patients are also immunocompromised and have at least one associated high-risk factor like older age, obesity, smoking, diabetes mellitus, ischemia secondary to vascular disease, irradiation, etc. that predisposes them to infection.”

Agarwal also noted, “I am interviewing but this research was fostered by Dean Steve Garfin, Profs. Jeffrey Wang, Neel Anand, Anand Agarwal, Vijay Goel, Chris Karas, Hossein Elgafy, Christian Schultz, Boren Lin, Dennis McGowan, Josue Gabriel and many more spine surgeons, scientists and hospital staffs.”

“The clinical evidences that what we have generated was a result of countless collaborations and effort over multiple institutions.”

“In addition to our extensive research work, I also recommend interested readers to other studies like Rehman et al. (2015) for glove change before handling pedicle screws, Leitner et al. (2018) for identifying the association between pedicle screw loosening and bacterial growth at the interface, Eren et al. (2018) for exemplifying reduction in deep bone SSI by disinfecting pedicle screws intraoperatively, etc.”

“We together are engaged in making the fair and evidence-based choices for patients; in absence of an appropriate regulatory or policy oversight on such matters. Hopefully that will follow soon.”

Amen! ♦

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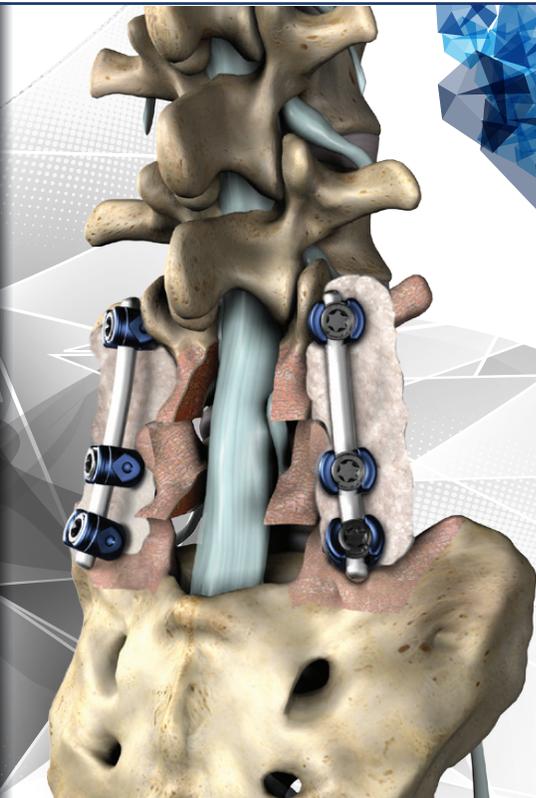


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# Orthopedic Practice Consolidation Jumps 45% in 2018

BY JEFF SWEARINGEN, GUEST WRITER FOR OTW

**L**ike it or not, healthcare industry consolidation is a fact of life for medical professionals.

What's driving this trend? More complex and uncertain reimbursement practices, increasingly burdensome administrative duties inflicted on physicians and a deep and abiding desire to return to the practice of medicine.

Adding to these factors are changing models of care delivery that require financial resources and an investment of capital unavailable to most physician practices.

In the first six months of 2018, 94 physician groups elected to sell or merge their practices, up 45% from the record setting transaction volume of 2017. More are on the way.

The good news for orthopedic practices is that the specialty has become a very attractive investment for private equity (PE) firms that see value in the consolidation trend and will pay well to participate in this trend.

## Benefits for Physician Owners

Private equity investors bring two important benefits for orthopedic practice owners:

1. The ability to cash out a portion of their practice equity at historically attractive valuations; and,
2. The ability to access additional capital and expertise to accelerate further practice growth.



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Outside investor participation can accelerate growth in several ways, including providing capital and expertise for mergers and acquisitions, resources and relationships for market expansion, and capital for facility growth and information technology (IT) investment.

## Mounting Capital Requirements and Operating Pressures in Orthopedics

Patients and commercial payors like ambulatory surgery centers (ASCs).

They offer lower costs per case, improved technology, patient preference, 23-hour stay programs, and significant improvements in anesthesia and postsurgical pain management.

If payors had their way, a significant portion of orthopedic procedure volume would move to outpatient settings.

Centers for Medicare and Medicaid Services (CMS) is also changing incentives to favor ASCs.

Orthopedic groups interested in expanding and building a state-of-the-art ASC however, require capital. The cost of building an ASC averaged \$413 per square foot in 2013. It's probably higher now. A small center with two surgical suites will range from \$2 to \$3 million, while a larger orthopedic ASC with integrated imaging, physical therapy (PT), and other ancillary capabilities can cost more than \$10 million to develop.

Beyond the cost of facility expansion, orthopedic groups face several other demands for scarce capital and management time. CMS and other payers expect orthopedic physicians to prac-

tice medicine within a bundled reimbursement scheme. These programs typically employ pre-negotiated rates and fixed price services and shift risk and cost burdens to the orthopedic physician from pre-op through a post-op and the 60-90-day rehab period.

Successfully navigating this outcome-based reimbursement and population management requires a substantial investment in data analytics—to say nothing about a new IT infrastructure to control all the variables including post-op PT and outcome metrics.

The Merit-based Incentive Payment System (MIPS) reporting requirements create additional uncertainties and risk to future incomes (tying reimbursement levels to performance metrics on a relative scale). Costs are bound to rise.

Data from a recent survey of approximately 100 physician groups showed that most believe they must have at least 200 physicians to pay the \$500,000 or more for IT required for MIPS participation. Only 19% of respondents told the survey that they are confident or very confident in their MIPS capabilities.

Further complicating this picture are the competing constituencies across the payor-provider continuum. Payers are rapidly consolidating and building negotiating leverage over physicians.

In the past 10 years, more than 500 hospitals have merged into larger health systems. More than \$100 billion has been spent on hospital consolidation in the last six years alone.

The top three publicly traded payors now have a combined enterprise value

of more than \$350 billion, providing scale, negotiating leverage and almost unlimited access to capital.

All of these external pressures are putting the burden on physicians to decrease costs while improving outcomes.

No wonder physicians are, themselves, consolidating in order to also build scale to counter the emerging hospital and commercial payor behemoths.

### Outside Investment Zeroes in on Orthopedics

Until recently, few outside private equity investors were interested in orthopedic practices. That is changing.

In January 2017 Frazier Healthcare Partners invested a reported \$50 mil-



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lion in the CORE Institute. Several other practices, including The Orthopaedic Institute, followed suit shortly thereafter and partnered with private equity investors.

Today, there are at least a half-dozen large and mid-sized orthopedic groups in negotiations with private equity investors.

These groups understand that the orthopedics industry is exceptionally well positioned for investment and consolidation. Many conditions such as an aging population and joint damage caused by obesity are providing strong underlying demand for orthopedic services, give PE investors' confidence in the market.

### Other Reasons Capital is Flowing into Ortho Practices

Spine, orthopedics and sports medicine practices are poised to benefit from recent changes in reimbursement—including CMS' focus on the relatively high cost of procedures in the inpatient setting compared with an ASC—which can only help to drive more patient volume to the outpatient centers. Spine, orthopedic and sports medicine practices with the resources and scale to take advantage of these trends should see attractive growth for many years to come.

### The Formula for Growth

The faster growing practices are creating platforms with a broad array of services, such as PT, urgent care, MRI, and pain management, which create highly effective patient volume magnets.

Private equity can help to fund this growth.

Most private equity-based transactions are structured so that the investor group buys a majority or minority stake in the practice—generating significant cash proceeds for physician shareholders.

At the same time, the new capital creates a vehicle for growth—both by funding a platform of services and creating the potential for mergers with other orthopedic groups. Under these scenarios, selling physicians continue to own a significant stake in their practice and manage the day-to-day clinical operation while retaining the opportunity to benefit economically from accelerated growth in the practice, in terms of both increased income and equity appreciation.

Consolidation is happening on both a national and a regional level. As this occurs, it will place additional competitive pressures on smaller practices, and likely

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trigger more transactions. Radiologists, dermatologists, ophthalmologists, and other specialty groups are further down the road in this process and provide a road map for what orthopedics can expect.

There are multiple factors to consider when buying or selling a practice or

joining with a private equity firm to grow in a consolidating environment. These include everything from practice valuations to taxes to real estate considerations. Most physicians will only go through this process once, so professional guidance is critical to maximizing value and avoiding potential issues.

If, and when, the decision is made to sell or pursue a strategic partnership/investor, understanding both the broad market dynamics, and your interests as an owner of an orthopedic practice, will be vital in maximizing value. ♦



Jeff Swearingen is co-founder and Managing Director at Edgemont Capital, a leading healthcare investment banking firm. Edgemont Capital has represented dozens of independent physician practices in mergers, acquisitions, and private equity transactions. (<http://www.edgemontcapital.com/>)

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# Gehrke v. Sculco: Routine Use of Antibiotic Bone Cement in Primary TJA is Justified

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 18th Annual Current Concepts in Joint Replacement® (CCJR®), Spring meeting, which took place in Las Vegas. This week's topic is "Routine Use of Antibiotic Bone Cement in Primary TJA is Justified." For is Thorsten Gehrke, M.D., ENDO-Klinik, Hamburg, Germany. Opposing is Thomas P. Sculco, M.D., Hospital for Special Surgery, New York, New York. Moderating is Daniel J. Berry, M.D., Mayo Clinic, Rochester, Minnesota.

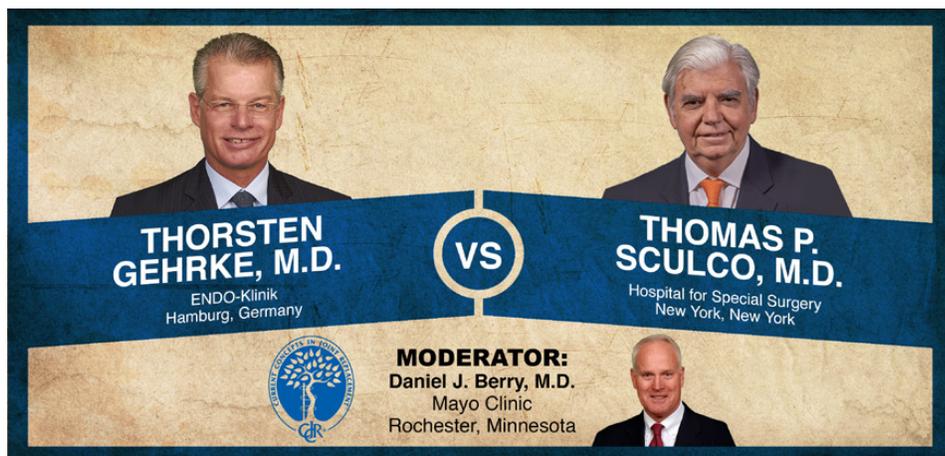


Photo creation by RRY Publications

**Dr. Gehrke:** The story of antibiotic bone cement started with Buchholz and Lodenkamper—two microbiologists who had the idea to mix antibiotic to the bone cement. Buchholz wrote a letter—almost 50 years ago—to a company that produced bone cement and asked them to mix antibiotics with their cement. The company agreed. He found that he could reduce the infection rate to 0.5%.

One of Buchholz's good friends, Sir John Charnley, said to him in a letter 'nothing leaks out of a stone, my dear Buchholz'. But his friend was wrong. We now know there are two kinds of antibiotic release from bone cement. First, the highest release of antibiotics out of the bone cement is within the first 10-20 minutes. And then after that is the second phenomenon of a very low, but very stable level of antibiotic leakage. During the first two hours you can reach such a high concentration that you have 1,000 times higher than MICs for staphylococci, for example.

Not every antibiotic behaves the same way. For example, vancomycin is bad regarding the release. It's released only for the first 2-3 weeks and then it stops. It's not the best antibiotic for the bone cement. And another issue is that the release depends on the surface properties of bone cement. Cement that incorporates water quickly is the better for antibiotic elution.

There are two kinds of industry manufactured antibiotic loaded bone cement—gentamicin and vancomycin or gentamicin and clindamycin. We did a clinical trial for both of them. The question was, "Are there any side effects if we add antibiotics to the bone cement?" We looked after 20 patients and the antibiotic concentrations. And we found that we can be really, really relax because at maximum concentrations in the serum are far below the toxic concentration.

Is there any evidence? The Norwegian registry showed that the outcome of the antibiotic loaded bone cemented stems

are much better than the unloaded. If you look at a systemic review (*PLOS* 2013), all studies without any exception favor the antibiotic loaded bone cement.

And the Finnish registry where they looked after more than 43,000 knees, they came to the conclusion that the lack of use of antibiotic impregnated cement had a more dramatic effect than did the lack of use of intravenous antibiotics.

In Norway, again, much better results with antibiotics. That led to the fact that in the UK almost 100% of the surgeons are using antibiotic loaded bone cement routinely. Because they have seen that the cost effectiveness and the risk of infection is much, much lower.

A randomized study from Warwick, Great Britain (Sprowson AP, *Bone Joint J*, 2016), showed that the use of dual antibiotics in routine use significantly reduces the rate of SSI [surgical site infection] compared with standard.

Spanish investigators found (Sanz-Ruiz P, *J Arthroplasty* 2017), before they put antibiotics in the bone cement they had an infection rate of 4.3% for the hips and after 1.8%. This is a significant difference.

Is it evidenced based? No, it isn't. There is still no evidence-based study. I'm coming closer to you, Tom. But despite that, in Australia and most other countries, surgeons use antibiotics in 100% of the bone cement.

The International Consensus is that antibiotic impregnated bone cement reduces the incidence of infection—but it should be selected only for patients at higher risk.

**Dr. Sculco:** When it comes to the use of antibiotic composites in primary joint replacement, well I think we may have a little difference of opinion.

There is no question that periprosthetic joint infection is a huge, catastrophic complication. But infection rates have definitely declined. Use of parenteral perioperative antibiotics, better surgical techniques, speed of surgery ... lots of things we've done to reduce the incidence of infection. In the literature today, the incidence is anywhere between, in the best of centers, 0.1% to around 1%.

The other problem I see in North America is 90 - 95% of our hips are non-cemented.

No question. There is a place for it—high risk patients, as Thorsten just said—I agree with him 100%. I think you should use it in the primary knee; history of previous infection; diabetic; immunosuppressed; inflammatory arthritis. All a good place to use it. And in revision surgery—100% agree with him.

But there are some disadvantages to using it routinely. Cost is one. The emergence of resistant organisms is another. Alteration of mechanical properties is a third. If you get carried away and you use more, certainly you can impede the mechanical properties.

If you look at cost, our implant and antibiotic costs are ridiculously high. Antibiotic cement can add anywhere between \$450 and \$900 to a case. Under bundled payment programs, the increased cost of the antibiotic-loaded cement is not going to be reimbursed. So, it's going to be less revenue to the institution ultimately for that event.

I did a little math here and if we do 500 knee replacements, because that's the population I think it would apply to in the United States, and let's say there was a 50% utilization by our surgeons, the additional cost to the system ... if

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you look at \$500 as the added cost ... would be around \$125 million. Now if you calculate a high infection rate for total knee replacement of 1%, for it to be cost effective, you would have to reduce the infection rate to 0.04% to be cost neutral, which would be literally impossible.

Now, what about emergent bacteria? Certainly, mutation in organisms is a problem.

Some quotes from microbiologists and people who study this: "As might be expected from Darwinian evolution antimicrobial usage exerts a selective pressure favoring the emergence of antibiotic resistant organisms." Another economist and microbiologist: "Antimicrobial resistance is driving up healthcare costs, increasing the severity of disease and increasing the death rate from certain infections."

An organism can, in fact, grow on these antibiotic-loaded bone cements and can be exposed at sub-inhibitory levels, which induces bacterial mutation.

Looking at revision surgery, when primary bone cement with antibiotics was used, 88% had gentamicin resistant bacteria. They mutated very quickly. By contrast, in 57 revisions where antibiotic cement was not used in the primary, only 16% had resistant organisms.

A very, very good study by the Canadian government which looked at randomized trials, meta-analysis and systematic reviews concluded that "antibiotics in cement may not confer any benefit over plain cement in total knee and total hip."

The Norwegian registry, which was quoted, you need to reduce the infection rate 2.4-fold for it to be cost effective.

The Australian registry, which Thorsten just mentioned, 100,000 total knees, risk of revision for infection same with or without the use of antibiotics in cement.

Kaiser registry, 26,000 total knee replacements, no difference in infection rate with or without antibiotics,

So, in summary, I think the problems are that it is not cost effective, it can increase bacterial resistance (I think that is a real potential problem) and it's primarily useful in that high risk primary or revision knee.

**Moderator Berry:** Thorsten, any quick rebuttal?

**Dr. Gehrke:** First of all, I accept, for example, your cost issue in the U.S. We don't have it in Germany. The development of resistance of the organism was



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based on just two papers – again, never proven. Very low numbers. Fourteen cases. One other comment, we should differentiate between hip and knees. All Australian registry data were about knees. And the hip literature is a little bit different.

**Dr. Sculco:** I think you're absolutely right, Thorsten. If you look at the registry studies that you were quoting that were used in Scandinavia and the UK, the results are better in the hips than the knee, no question.

**Moderator Berry:** Okay, so a couple of areas of consensus. The data are stronger for or at least some benefit of antibiotic laden cement in the hip than the knee. In North America there's not many cemented hips done any more so it may be less clinically relevant. And it seems like the knee is less well accepted at least in terms of the literature. Would you both agree with that statement?

**Dr. Gehrke:** Yes.

**Moderator Berry:** Now I heard both of you say that you had an area of consensus and that was the high-risk patient, undergoing surgery. You both said if you're going to use cement, that is the patient who's got immunosuppression, complex surgery, revision surgery ... you'd use antibiotic laden cement. Did I get that correct from both of you?

**Dr. Sculco:** Yes, definitely.

**Moderator Berry:** There was consensus. But let me ask you the following question. If there's a benefit to the high-risk patient, why wouldn't you say that there is probably some benefit to the lower risk patient?

**Dr. Gehrke:** Of course, it's true. If you are seeing a very good benefit for the high-risk patient there is, of course,

benefit for the low risk patient at a lower level.

**Dr. Sculco:** I think so, but as I said, I think the downsides to the lower risk patient are greater. And I don't think therefore its widespread use in that population is indicated.

**Moderator Berry:** About this question of antibiotic resistance, Thorsten, I think you're probably right. The data is pretty weak. Our bacteriologist tells us that the likelihood of resistance emerging in a closed environment, like the hip or the knee—closed wound—is very, very low. Is that what your microbiologists say?

**Dr. Gehrke:** Exactly the same.

**Moderator Berry:** Tom, you did a nice job of bringing out this cost effectiveness question. What about mixing the antibiotic yourself and I'll

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just say that's an off-label use, but it's far cheaper than using the pre-mixed stuff?

**Dr. Sculco:** There is a question as to whether the elution properties are as good if you hand mix it than if it's commercially done. We did a study where we looked at using liquid gentamicin and the problem is that it is detrimental to the mechanical properties, but in a spacer, you can use liquid gentamicin for \$3 for a little vial.

**Moderator Berry:** Tom, in your high-risk patient, what are you typically using for cement? Not brand names, but just in terms of what antibiotics?

**Dr. Sculco:** Palacos gentamicin is the one I would ordinarily use. If it's a particularly high-risk patient that has a previous history of infection, I'll probably add 500mg of vancomycin to that and mix it in.

**Moderator Berry:** Thorsten, how about you?

**Dr. Gehrke:** The same, absolutely the same. And if you are operating on a patient on a high risk or who has a history, for example, of MRSA infection, we use the industrially manufactured bone cement, which contains 1g gentamicin and 1g vancomycin.

**Moderator Berry:** That's my pattern as well. Please join me in thanking the two speakers for a great session. ♦

Please visit [www.CCJR.com](http://www.CCJR.com) to register for the 2018 CCJR Winter Meeting, – December 12 - 15 in Orlando, Florida.

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COMPANY

## Daniel Abromowitz: New GM Spine for Medacta USA

Daniel Abromowitz is now at the helm as General Manager of the Spine Division for Medacta USA, a company headquartered in Castel San Pietro, Switzerland.

The former vice president of sales and business development at Captiva Spine, Abromowitz also served as vice president of sales and marketing at Aerobiotix, Inc. As VP of sales at Xtant Medical Abromowitz managed 50 direct sales managers and sales representatives along with over 300 independent distributors. He also spent seven years as vice president of sales at X-spine Systems, Inc.

Daniel Abromowitz told OTW, "I'm thrilled to join the Medacta USA team as General Manager of the Spine Division. Looking ahead, my priorities are focused on expanding the use and adoption of our MySpine product portfolio, increasing our sales presence across the U.S. and preparing for the 9th M.O.R.E.

International Symposium, which will be held April 11-13, 2019 during which Medacta International will celebrate its 20th Anniversary."

"As a passionate supporter of collaborative worldwide innovation, Medacta International offers an incredible growth opportunity for spine in the U.S. market. My goal is to build on the successful foundation of Medacta's joint division here in the U.S. to support our key stakeholders in spine: surgeons, patients, facilities and agents," Abromowitz said. "By utilizing the Medacta Orthopaedic Research and Education (M.O.R.E.) Institute, Medacta surgeons are never alone. I hope to expand on these peer-to-peer training programs for spinal surgeons here in the U.S., as we build Medacta USA Spine into an innovative leader for the U.S. market."

"Daniel is a welcomed addition to the management team, bringing an innovative management approach and broad engineering and supply chain experience," said Eric Dremel, president of Medacta USA. "Most importantly, Daniel's track record of sustained commercial success and relentless customer focus will allow the potential of our Spine Division to be fully realized." — EH



Daniel Abromowitz / Medacta USA

## Stuart Kleopfer, New Senior VP of Global Sales at Exactech

Stuart Kleopfer, a 30-year veteran of the ortho "universe," is the new senior vice president of global sales at Gainesville, Florida-based Exactech, Inc.



Stuart Kleopfer / Courtesy of Exactech, Inc.

According to the company, "Kleopfer will provide leadership for Exactech's global sales functions with responsibility for the United States sales organization and the company's current international team. He had a distinguished career at Biomet that included serving as president, U.S. Commercialization, and then with Zimmer Biomet where he served as president, Americas, until 2017."

According to company CEO David Petty, "Stuart is a great addition to Exactech and an excellent fit for our surgeon-focused culture. It's an exciting time of growth for the company and we are eager to leverage Stuart's expertise."

Exactech Co-Executive Chairman Jeff Binder also commented, "We are excited to add Stuart, with his proven track record of success, to the Exactech team and I am looking forward to working with him again."

Kleopfer told OTW, “I will first focus our global sales force on all of our products in Hip, Knee and Extremities. I am also eager to engage with our surgeons and hospitals to see how we can better serve them and their patients.”

“The Exactech culture, which is very surgeon and sales rep centric, is very refreshing to be a part of since it is so similar to the legacy Biomet culture that I enjoyed. We will also be having representatives from our global team and sales forces together for the first time to better coordinate product lines and drive top line revenue around the globe.”

“My entire career at Biomet prepared me for my current role. No matter what position you were in, we always stressed that we had two customers: first are surgeons and hospitals and the second are our sales representatives in the field. If you are not treating your sales reps as a customer and they are not aggressively promoting your products, your success will obviously be impacted.” — EH

LEGAL

## After Two Decades Will Dr. Menkowitz Get Justice?

Orthopedic surgeon Dr. Elliott Menkowitz has been fighting in court for over 20 years against Peerless Publications, Inc. for publishing articles that allegedly tarnished his career.

In April 1996, John Buckley, the president and CEO of Pottstown Memorial Medical Center (“PMMC”), “... told Dr. Menkowitz that his behavior of yelling

at staff was unacceptable” and “... conveyed the Medical Executive Committee’s (“MEC”) decision “to suspend Dr. Menkowitz’s staff privileges or allow him to take a voluntary leave in an attempt to address his behavioral concerns ....”

Dr. Menkowitz told Buckley that he had been diagnosed with attention deficit disorder (“ADD”) and was taking medicine for his condition. As a result, in lieu of suspension, the MEC issued a stern warning that it would not tolerate verbal harassment of other physicians or employees.

However, about a year later, Dr. Menkowitz’s privileges were suspended because, according to the Pottstown Memorial Medical Center’s Medical Executive Committee, Menkowitz’s disruptive and unacceptable conduct continued to be a concern.

Soon thereafter (April 1997), the local Pottstown paper, *Pottstown Mercury Newspaper*, published several news articles which stated, among other things, that his absence from the hospital had “spawned rampant rumors of professional misconduct regarding his treatment of an older female patient.”

On April 14, 1998, Menkowitz filed a defamation lawsuit against the news-

paper and sought over \$1 million in damages.

According to his testimony at trial, Dr. Menkowitz said that he fell into a deep depression after reading the *Pottstown Mercury Newspaper* articles. He further testified that the medications he received from his doctor to treat his depression caused fasciculations and tremors in his arms and hands, which was supported by expert testimony.

Bottom line: Dr. Menkowitz testified that the article-induced depression impaired his ability to perform surgery.

Peerless Publications (publisher of the *Pottstown Mercury Newspaper*) responded with arguments that its articles were not misleading and had been published in good faith, and Dr. Menkowitz’s injury to reputation and emotional and psychological injuries were caused by his suspension.

On March 2014, the jury sided with Menkowitz and awarded him \$800,000 for past and future lost earnings, \$200,000 for harm to his reputation, and \$1 million in punitive damages.

Peerless Publications filed post-trial motions which led to the trial court vacating the punitive damages award



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based on its finding that there was no evidence of malice. Dr. Menkowitz filed an appeal seeking to reinstate the punitive damages award, and the newspaper cross-appealed to vacate all damages.

It turns out, Dr. Menkowitz' appeal may not have been in his best interests.

The appeals court said because Menkowitz failed to show evidence of malice by the newspaper, he would only be entitled to damages if he could prove that his reputation was directly injured by the alleged false statements.

The Pennsylvania Superior Court found that any evidence of damage to his reputation stemmed from the suspension, not any implication of sexual or physical abuse from the news articles.

On December 15, 2017, fully 20 years after the original articles were published in the *Pottstown Mercury Newspaper*, the Pennsylvania Superior Court upheld not only the vacating of punitive damages, but vacated the entire judgment and compensatory damages award, leaving Dr. Menkowitz with nothing.

Of course, that's not the end of the story.

Menkowitz appealed and on August 2018, the Pennsylvania Supreme Court agreed to hear the case, where it will review the legal standards applied by the lower courts.

The case is scheduled to be presented to the state's highest court sometime in 2019.

Will Dr. Menkowitz be able to win back his damages, or will he be left in the dust after a grueling 20 years of court battles?

Or, will this Zombie case continue to live on in some, as yet unforeseen, form? — MK

## Whistleblower Nets \$5.4 Million in \$24 Million Settlement

Montana-based Kalispell Regional Healthcare System (KRH) and six of its subsidiaries and related entities have agreed to pay \$24 million to settle a whistleblower lawsuit with the Department of Justice (DOJ).

In a two-year investigation, the Department of Justice uncovered evidence that 63 physicians were involved in an illegal kickback scheme with KRH. The DOJ alleged that the compensation arrangements between the hospital group and its physicians violated the federal Anti-Kickback Statute, the False Claims Act and the Stark Law, which prohibit physician self-referrals.

The illegal physician compensation scheme involved orthopedic surgeons, cardiologists, cardiovascular surgeons, gastroenterologists, internal medicine physicians, general surgeons, neurosurgeons, surgical oncologists, radiation oncologists, breast surgeons, neurologists, and gynecologists.

The government became aware of the violations when whistleblower Jon Mohatt filed two lawsuits under the False Claims Act, which allows private parties to bring suits on behalf of the government and to share in any recovery. Mohatt was formerly the Chief Financial Officer of KRH's Physician Network. Mohatt will receive \$5,411,521 million as his share of the recovery.

Following the settlement, United States Attorney for the District of Montana Kurt Alme stated, "Quality healthcare is a critical

need of all Montanans, but paying extra to physicians to induce referrals improperly raises the cost of that healthcare and must stop ... I would like to thank the team that worked hard to bring this to a quick and successful resolution, which is the largest False Claims Act recovery in the District of Montana, including members of the U.S. Department of Justice and U.S. Attorney's Office, as well as agents with the Department of Health and Human Services-Office of Inspector General and the Federal Bureau of Investigation."

OTW spoke with Bryan Vroon, lead counsel and spokesman for the whistleblower Jon Mohatt. Vroon has served as lead counsel for whistleblowers in 85 settlements involving false claims against federal healthcare programs resulting in over \$384 million in recoveries to the Federal Treasury since 2010.

Vroon said, "Orthopedic surgery is a lucrative service line for hospital systems. Physician compensation packages that take into account the value of orthopedic admissions or procedures to the hospital system are detrimental to the Medicare Program and violate the Stark Law. Whistleblowers can have a significant impact if they are willing to step forward in the interests of Medicare, Medicare patients, and American taxpayers." — KD



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## FDA Releases Medical Device Guidance for 2019

What guidance can you expect from the FDA's Center for Devices and Radiological Health (CDRH) for 2019? Risk-benefit determinations, unique device identification and 510(k) program expansions, to name a few. And now, they want to hear from you.

On October 5, 2018, the agency published three lists of guidance documents we can expect to see in the coming year. The lists are:

- The “A List” of guidance documents that the agency fully intends to publish;
- The “B List” of guidance documents that the agency intends to publish as resources permit; and,
- Finally, a list of final guidance documents issued in 2009, 1999, 1989, and 1979 that are subject to focused retrospective review.

The “A List” includes:

- *Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions*
- *Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and*
- *Direct Marking of Inventory*
- *Breakthrough Devices Program*
- *Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria*
- *The Least Burdensome Provisions: Concept and Principles*
- *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act*
- *Clinical and Patient Decision Support Software*

- *Multiple Function Device Products: Policy and Considerations*
- *Humanitarian Device Exemption (HDE) Program*
- *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*
- *The Special 510(k) Program*

### The FDA Wants to Hear From You

The agency says it would appreciate comments on any or all the guidance documents on the three lists to docket FDA-2012-N-1021. Specifically, the FDA seeks comments on the relative priority of guidance documents. Comments could also include draft language on the proposed A-list and B-list topics, suggestions for new or different guidance documents, for which they request that commenters state the potential guidance topic, reasons the guidance is needed, and proposed policy or information for FDA to consider on the topic.

You should submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with docket number FDA-2012-N-1021 for “Notice to Public of Website Location of CDRH Fiscal Year 2019 Proposed Guidance Development.” Submit electronic comments to <http://www.regulations.gov>.

To link to the FDA webpage for proposed guidance development information, [click here](#). — WE

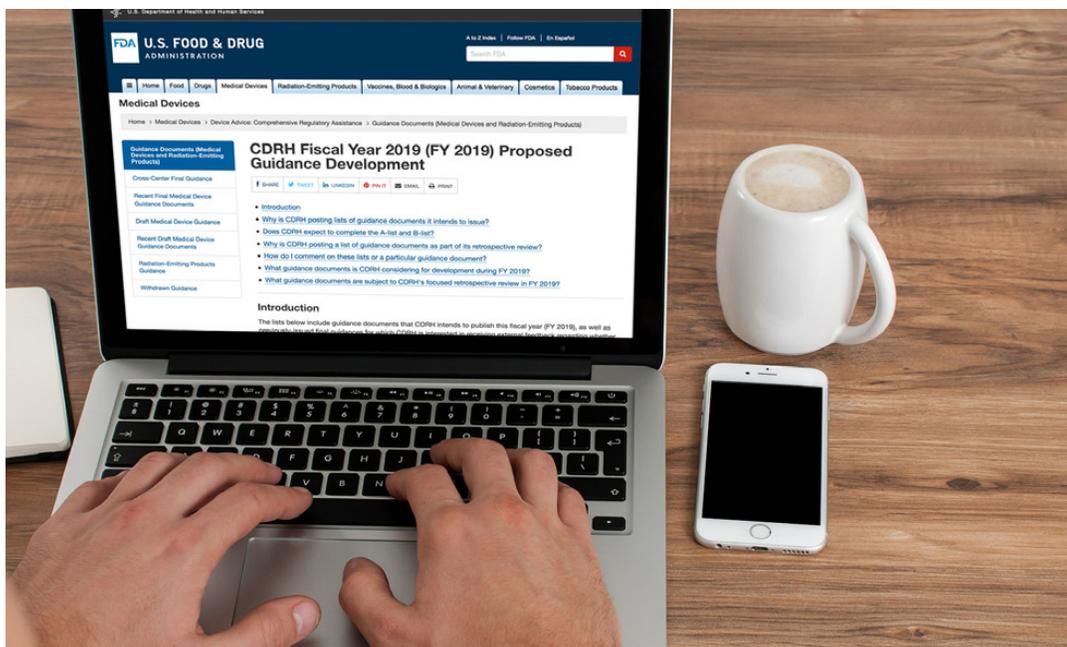


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## CMS to Pay Extra for Exparel in ASCs, Not Hospitals

The Centers for Medicare and Medicaid Services wants to give new money to ambulatory surgery centers (ASCs) to prescribe anything but opioids for immediate post-surgical pain—but not hospitals paid under the Outpatient Prospective Payment System (OPPS).

The proposal, in the [lengthy rule proposal](#) which aims to otherwise make payments site-neutral between hospital outpatient surgery centers and ASCs, says:

“... [W]e are proposing to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019.”

The CMS proposed rulemaking frequently mentions one analgesic, Exparel. It's currently the only branded drug approved by the Food and Drug Administration (FDA) as an immediate post-surgical local analgesic.

Exparel, a liposome injection of bupivacaine, was first approved by FDA in 2011 as a post-surgical anesthetic for bunionectomy and hemorrhoidectomy only. In 2015, FDA, allowed the

vendor, Pacira Pharmaceuticals, Inc. to sell the drug as a post-surgical anesthetic for a broad range of surgeries. FDA also approved Exparel on April 6, 2018, for use as an interscalene brachial plexus nerve block after surgery.

### Why only ASCs, not hospital outpatient surgery centers?

CMS temporarily gave Exparel “pass-through” status—that is, separate reimbursement from bundled surgical supplies—in calendar years 2012 through 2014 in both the hospital outpatient and ASC settings, then withdrew separate-reimbursement status for both settings.

“From CYs 2013 through 2017, there was an overall increase in the OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) ... The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) ... This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from CYs 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period

(from 28,166 claims to 34,183 claims).”

However, in ASCs, the end of separate payment had an opposite effect. CMS says, “there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of CYs 2013 and 2014 when the drug received pass-through payments.”

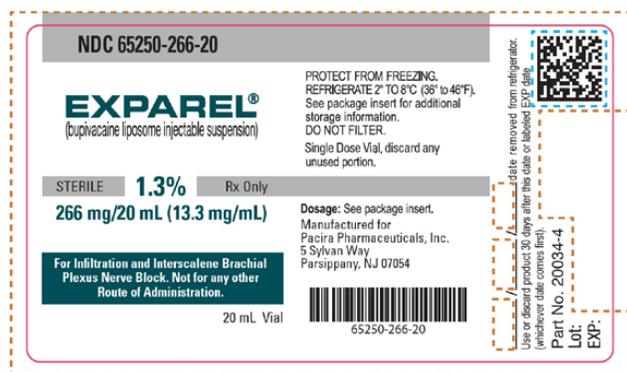
When the pass-through ended, “In the ASC setting ... the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between CYs 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims).”

Two other factors behind the CMS plan are:

- A recommendation by the [President's Commission on Combating Drug Addiction and the Opioid Crisis](#) (the Commission) that CMS “review and modify ratesetting policies that discourage the use of nonopioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.”
- The Department of Health and Human Services (HHS) April 2017 [Five-Point Opioid Strategy](#) which, CMS said, “aims in part to support cutting-edge research and advance the practice of pain management.”

### CMS Isn't Convinced of Its Own Plan

The rulemaking proposal admits that it needs “... peer-reviewed evidence that demonstrates that use of non-opioid



Courtesy of Pacira Pharmaceuticals, Inc.

alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking comments containing the types of evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.”

The proposed rulemaking also acknowledges that CMS is in the dark as to whether to allow unbundled payment for other non-opioid pain treatments:

“We are specifically interested in comments regarding whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPI and the ASC payment system that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted.”

CMS is also asking whether certain pain management devices which already have pass-through status are reducing opioid prescriptions.

These include “spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463 and 5464 (Levels 3 and 4 Neurostimulator and Related Procedures).”— WD

## LARGE JOINTS

### Unicompartmental Knee Arthroplasty for ALL Patients?

Multicenter research is suggesting that surgeons might consider doing a unicompartmental knee arthroplasty in all patients. The study, “[Cost-Effectiveness of Surgical and Nonsurgical Treatments for Unicompartmental Knee Arthritis: A Markov Model](#),” is published in the October 3, 2018 issue of *The Journal of Bone and Joint Surgery*.

Antonia Chen, M.D., M.B.A., with the department of orthopedics at Brigham and Women’s Hospital, Harvard Medical School in Boston, Massachusetts, told OTW, “In this era of value driven care, it is important to assess surgical and nonsurgical options with regards to their cost-effectiveness. With younger patients undergoing arthroplasty surgery, and longer life expectancy of patients, it is important to understand the most cost-conscious manner of treating our patients to provide them with a high quality of life while reducing costs to society. This modeling study was able to evaluate a larger breath of patients, and assess which approach was ideal for treating patients with unicompartmental knee arthritis.”

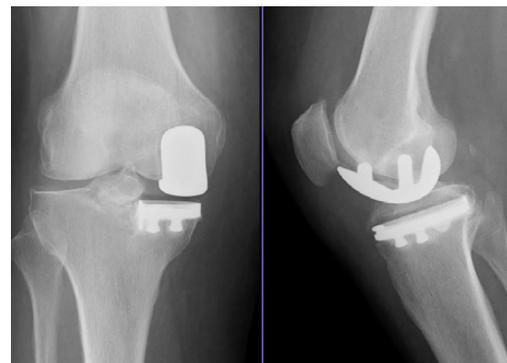
For the study, the authors used a Markov decision analytic model which “assessed how lifetime costs and quality-adjusted life years (QALYs) vary as a function of age at the time of initial treatment (ATIT) of patients with end-stage unicompartmental knee osteoarthritis undergoing TKA [total knee arthroplasty], UKA [unicompartmental knee arthroplasty], and NST [nonsurgical treatment].”

“A Markov decision process is a discrete time stochastic control process. It provides a mathematical framework for modeling decision making in situations where outcomes are partly random and partly under the control of a decision maker,” as defined by Wikipedia.

Dr. Chen said that the team “found that unicompartmental knee arthroplasty was universally the best treatment option for unicompartmental knee arthritis until the age of 87.”

“Quality-adjusted life years was higher at all ages, but surgical intervention with unicompartmental knee arthroplasty was only cost-effective until the age of 87 years. Surgical intervention with total knee arthroplasty was only cost-effective until 81 years old. At the age of 70 years, the costs of surgical treatment exceeded the costs of nonsurgical treatment, but the large benefit from surgical treatment resulted in an incremental cost-effectiveness below the willingness-to-pay threshold.”

“The most interesting take-home message from this work is to not discount surgical management in younger and older patients suffering from unicompartmental knee arthritis. Additionally, consider doing a unicompartmental knee arthroplasty in all patients, if possible.” — EH



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SPINE

## Vertos: MOTION Study of MIS Decompression Using Fitbits

Vertos Medical Inc. has enrolled the first patient into its nationwide, multicenter study of its minimally invasive lumbar decompression (aka: *mild*®) procedure and will be using the popular device, Fitbit, to collect data.

According to the company, “The novel, prospective, randomized controlled study will use clinically validated, patient-reported outcome measures to identify improvements in pain and function, and will capture objective measures of participants’ activity levels using Fitbit activity trackers.”

The procedure being studied is an outpatient lumbar decompression procedure which treats the patient’s stenosis “... through a portal the size of a baby aspirin. The Vertos procedure “... requires no implants, no general anesthesia, no stitches, and no overnight hospital stay.”

The company’s study of this approach will follow patients who been treated with this *mild*® procedure for two years and, the company expects, “... will enroll patients 50-80 years of age and will provide important data to help physicians and patients make early treatment decisions for other LSS [lumbar spinal stenosis] sufferers.”

The study, which is branded the “MOTION

Study” recently enrolled its first patient at the Michigan Interventional Pain Center in Brownstown, Michigan. The physician who will perform the inaugural *mild*® procedure was Razmig Haladjian, M.D., an interventional pain specialist.

“A major step forward in interventional pain occurred with the first patient enrolled in the MOTION Study, a level 1, prospective, randomized, multicenter study that evaluates subjective and objective functional measures,” said Dr. Tim Deer, an interventional pain specialist, president and CEO of The Spine and Nerve Center of the Virginias and national principal investigator for the MOTION Study.

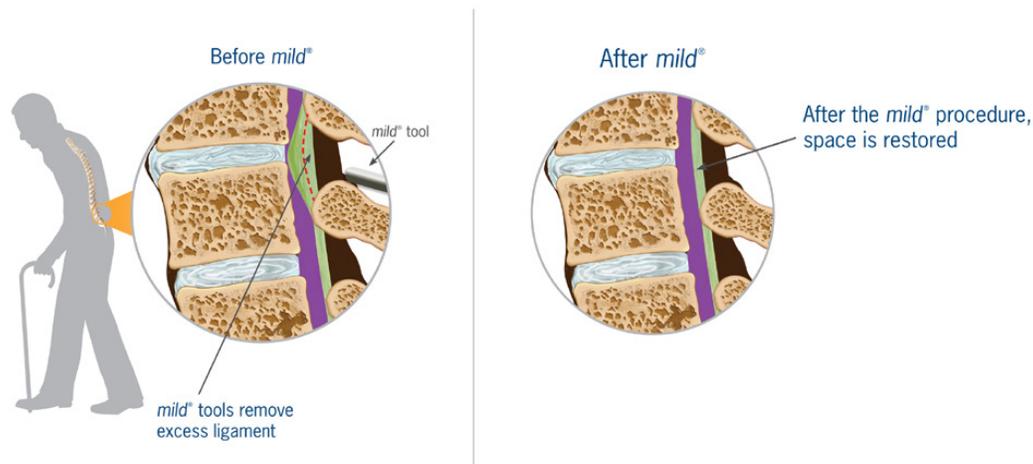
“This important, activity-based study will generate evidence that further supports minimally invasive LSS treatments to improve patients’ quality of life and reduce the use of opioids,” added Dr. Deer.

Eric Wichems, president and CEO of Vertos Medical, told OTW, “The primary endpoint for the study is Oswestry Dis-

ability Index (ODI) at 6 months, which measures permanent functional disability using questions regarding activities of daily living (ADL), specifically disturbance in ADL related to chronic back pain.”

“Other measures include 6-month follow up on pain intensity, severity of symptoms, physical function characteristics, and patient’s satisfaction after treatment along with steps/walking distance measured by a Fitbit activity tracker and walking time. Consistent measures will be taken at timepoints leading up to study completion at two years.”

“The *mild*® procedure removes the root cause of neurogenic claudication, by debulking the ligamentum flavum, the major contributor to spinal canal narrowing. It is the clinically demonstrated safest decompression procedure with clinically proven effectiveness in patients with comorbidities. The *mild*® procedure has been performed on more than 20,000 patients and its safety and efficacy have been analyzed in more than 13 clinical studies and 20 publications.” — EH



Courtesy of Vertos Medical Inc.

## ApiFix: 250+ Scoliosis Patients Treated

Boston, Massachusetts-based ApiFix Ltd. has announced that its Minimally Invasive Deformity Correction (MID-C) technology has now been used to treat more than 250 young patients diagnosed with progressive scoliosis. Another milestone is that the earliest treated patients have reached their six-year follow-up milestone.

According to the company, “ApiFix’s MID-C technology is a posterior dynamic deformity correction system that enables surgeons to perform a unique treatment providing permanent curve correction while retaining spine flexibility using a least invasive surgical approach.”

“Patient recovery is relatively pain-free and is measured in days, not months. The MID-C system acts as an ‘internal brace’ that incorporates a patented uni-directional, self-adjusting rod mechanism with motion-preserving polyaxial



Courtesy of ApiFix Ltd.

joints allowing additional non-invasive post-operative correction over time and is removable.”

“... A typical ApiFix surgical procedure takes about 90 minutes with minimal blood loss (~50cc) and short hospitalization and recovery times (1-2 days and 1-2 weeks, respectively). In contrast to fusion correction procedures, the MID-C system allows for additional deformity correction with standard post-operative exercises. Patients’ normal daily activities are unencumbered since spine flexibility and mobility are retained.”

“Despite great recent advancements, our options to address progressive curvature in young patients today remain limited,” said Randy Betz, M.D., past president of the Scoliosis Research Society. “Bracing systems are required to be worn many hours per day and do not correct the deformity.”

“Standard spinal fusions correct the deformity but have a much longer recovery time and result in a permanent loss of mobility. The introduction of a procedure that can effectively correct spinal deformity with less invasive, motion-preserving techniques will have a dramatic effect on the quality of life for these patients and their families.”

Paul Mraz, ApiFix CEO, told OTW, “The unique ApiFix approach provides a viable alternative to bracing and spinal fusion for many patients as the least invasive spine deformity correction option. Scoliosis affects 2%-3% of the world’s population—these are the patients—but it also impacts their families and all of the doctors and caregivers they will come to know along the way. So, our work at ApiFix provides us the opportunity to make a significant positive impact on the lives of millions of people around the globe.” — EH

## REIMBURSEMENT

### DC Legislation Roundup: Research Funding News, Sports Licensure

Most of the benefits for orthopedics survived a House-Senate conference when President Donald Trump signed that Defense-Labor-HHS “mini-bus” appropriations bill on September 28 (“[Major Increase in Ortho Research Funding on the Way](#),” *Orthopedics This Week*, September 13, 2018).



Wikimedia Commons and Office of the Speaker

“We are pleased to see a \$2 billion increase in funding for NIH [National Institutes of Health]—a sustainable level to help fund its much-needed basic and clinical research,” a spokesperson for the American Association of Orthopaedic Surgeons (AAOS) said. The extra \$2 billion might include an increase in funding for the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

The 21st Century Cures Act received the Senate’s proposed \$711 million, which provides funding for both new-device research, including orthopedic devices, and new pain management alternatives to opioids.

AAOS said two House recommendations to the Centers for Medicare and Medicaid Services (CMS) survived the House-Senate conference:

- One supports the quality of physician-owned hospitals (and impliedly hints that the Centers for Medicare and Medicare Services should lighten up on Stark-based rules suppressing Medicare reimbursements for them).
- The other urges CMS to pay for Qualified Clinical Data Registries (QCDRs), including the American Joint Replacement Registry (AJRR), now called the AAOS Orthopaedic Quality Resource Center. QCDRs help physicians receive merit payments and avoid penalties under the Merit-based Incentive Payment System (MIPS) component of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

The Defense Department's [Peer Reviewed Orthopaedic Research Pro-](#)

[gram](#) (PRORP), run by the U.S. Army Medical Research Materiel Command, is getting \$30 million in funding in the bill for fiscal year 2019, the same amount as FY 2018, a U.S. Army spokesperson said. PRORP offers grants for orthopedic research. The types of research funded by PRORP in FY 2018 can be seen by scrolling down this page: <http://cdmrp.army.mil/funding/reftable#19>

### Sports Medicine Licensure Bill Heads to President's Desk

As expected, the final version of H.R. 302, the "Sports Medicine Licensure Clarity Act of 2017" ("[Sports Medicine Bill Huge Victory for Orthopedists](#)" *Orthopedics This Week*, September 13, 2018), passed the U.S. Senate October 3. House and Senate sponsors had been negotiating final details of the bill since a prior Senate version passed September 6.

"For too long, team physicians have had to choose between treating patients at great professional risk or handing over care," said AAOS President David A. Halsey, MD. "Its passage represents years of hard work trying to get it across the finish line and it is a significant win—not only for practicing sports medicine professionals, but also for the large percentage of orthopaedists involved in the treatment and care of sports-related injuries."

AAOS and the American Orthopaedic Society for Sports Medicine (AOSSM) have been pushing Congress for the legislation since 2015. If signed by the President as expected, it would allow sports medicine professionals who travel with teams to treat athletes in other states and be covered by their medical liability insurance as if they'd done their work in their home states. — WD

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PEOPLE

**James Starman, M.D., Joins OrthoCarolina**

James Starman, M.D., a shoulder and knee specialist, has joined the OrthoCarolina practice. After graduating magna cum laude from the University of Notre Dame, Dr. Starman attended the University of Pittsburgh School of Medicine and then completed an internship, residency, and research fellowship at the Carolinas Medical Center. He then completed a sports medicine fellowship at the University of Virginia.

“As our company continues to expand we strategically look for physicians

to fill specific roles and needs in the regions and communities we serve,” said Cathie McDonald, Chief Operating Officer, OrthoCarolina.

Dr. Starman told OTW, “As I work to establish my new practice, I think it is important to take the time to establish relationships with potential partners in the community. Specifically, as a sports medicine physician, to reach out to local high school trainers and coaches, and create opportunities to highlight my skill set and provide educational events. One event I am working on currently is an educational program for high school students interested in a career in orthopaedics, whether as a surgeon or other member of the medical team. We are partnering with local schools, implant



James Starman, M.D. / Courtesy of OrthoCarolina

companies, and various sponsors to develop this event, with a goal of involving around 100 local students for a hands-on seminar about a career in orthopaedics.” — TR

**Brian Scannell, M.D. Joins OrthoCarolina**

Brian Scannell, M.D., a pediatric orthopedic surgeon, has joined the OrthoCarolina practice. Dr. Scannell graduated from the University of Georgia with Honors in Biology and then obtained his M.D. from the University of North Carolina School of Medicine. He attended the Carolinas Medical Center for an orthopedic research fellowship and an internship/residency.



Brian Scannell, M.D. / Courtesy of OrthoCarolina

He then completed a Pediatric Orthopaedic and Scoliosis Fellowship at Rady Children’s Hospital of San Diego.

“Superior training emphasizing exceptional patient care and outcomes is critical when we make physician hiring decisions,” said Bruce Cohen M.D., CEO, OrthoCarolina.

Dr. Scannell commented to OTW, “I am excited to join OrthoCarolina. I already have an established practice locally. I am excited for my patients to now be a part of OrthoCarolina as well. It will take some time for us to get fully up and running but we will get there.” — EH



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