

Orthopedics • This Week

WEEK IN REVIEW

4 Centinel Spine, After 41 Years, Exits Fusion to Focus on Motion >> Centinel Spine, a leading global medical device company known for addressing cervical and lumbar spinal disease through the most robust and clinically proven total disc replacement (TDR) technology platform, has sold its STALIF® and other fusion products business to Swiss-based Silony Medical International for an undisclosed amount.



7 How 'Political' Are Orthopedic Surgeons? >> How political is your "average" hip and knee surgeon? And, to what extent do they take advantage of opportunities to help craft governmental policies that influence their work, as well as the lives of patients?



9 AAOS and AMA Oppose Proposed CMS Physician Pay Cuts >> CMS's plan to cut the pay conversion factor 3.36% means that, adjusted for inflation, physician pay is down 26% since 2001. This is unconscionable and, with the AMA and AAOS leading the way, all physician groups are raising the alarm.



BREAKING NEWS

- 11 **510(k) Clearance** for Pediatric Tibial Intramedullary Fixation Rod
- 12 **FDA's Draft Guidance** for Patient-Matched Ortho Implant Guides
- 14 **New Shoulder System** Features Smallest Baseplate Yet
- 15 **How Fast Can Young TKA Patients Get Back to Sports?**
- 17 **One Surgeon's Experience Volunteering Internationally**
- 22 **Foot & Ankle Surgeon Ronald J. Bruscia Dies at 75**

For all news that is ortho, read on.



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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Rough week. 86% (19/22) of the public ortho stocks lost value over the previous 30-days. This past month's trading patterns are revealing. Big caps did best. Worth noting are two long-term valuation trends which underlie all ortho and spine. #1 is scale—doing more with less. Scaling up is the most certain wealth creation method in ortho today. #2 is the transition from artisanal, craft-based medicine to process-driven medicine. #1 and #2 support each other. Understanding the macro, explains much of the micro in ortho and spine space.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	6	Johnson & Johnson	24.97%	(2.45%)	Under Aldo Denti, DePuy Synthes has "mojo" and...momentum? So far this year, DePuy Synthes has handily beat Wall Street's expectations. Looks like a sustainable pattern.
2	3	ConMed	7.42	(5.64)	CNMD has beat Wall Street's guesses 3 out of the last 4 quarters. For the record, Wall Street thinks that, for the September quarter, sales grew 7% and EPS increased 8%.
3	9	Zimmer Biomet	19.88	1.74	ZBH and SYK were two rare ortho birds this past month. They increased in value. For ZBH, it's an increase from an overly low valuation basis—10th cheapest overall.
4	2	Integra LifeSciences	17.32	(9.27)	Having lost 9% of its value, IART is now the 3rd cheapest equity in ortho. The 11 analysts covering IART expect down earnings on just 2% sales growth for Q3. Surprise coming.
5	5	Pacira Biosciences	23.50	(11.32)	PCRX is making the fireside chat rounds, but investors are still selling. Now 11% cheaper than a month ago, PCRX is 2nd cheapest ortho stock. Nice earnings jump coming in Q3.
6	8	Medtronic	18.65	(4.08)	The trading pattern I alluded to in my overall comments finds expression in MDT and JNJ. Scale is now a major wealth producer and trend—which MDT epitomizes.
7	1	Bioventus	(5.33)	(25.82)	The cheapest, by far, orthopedic company is Bioventus. Short termers think BVS is a falling knife and stay away. Long term investors appreciate the value of BVS.
8	4	Xtant	(9.71)	(11.86)	Not cheap, but the most interesting ortho company, for sure. Only one analyst covers this stock. That's too bad. No company is more creatively building shareholder value than Xtant.
9	7	ZimVie	(5.96)	(15.69)	Despite no love from Wall Street, ZIMV will yet a gain be reporting about \$200 million in sales and higher EBTDA for Q3. At a mere \$260 market cap, ZIMV is 4th cheapest ortho equity.
10	NR	Stryker	19.40	3.38	It's been a long while since SYK appeared on the Power Rankings. Why? Too expensive. Still expensive, but a top performing stock in a bear ortho market is enough to land SYK at #10 this week.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG.V	\$0.28	\$18	55.75%
2	Stryker	SYK	\$285.28	\$108,343	3.38%
3	Zimmer Biomet	ZBH	\$116.85	\$24,417	1.74%
4	Nevro Corp	NVRO	\$19.28	\$696	-0.36%
5	SI-BONE, Inc	SIBN	\$21.15	\$850	-0.66%
6	Johnson & Johnson	JNJ	\$160.50	\$385,438	-2.45%
7	Anika Therapeutics	ANIK	\$18.30	\$268	-3.38%
8	Medtronic	MDT	\$80.27	\$106,802	-4.08%
9	Medacta	MOVE	\$133.72	\$2,674	-4.35%
10	MicroPort Scientific	0853	\$1.57	\$2,874	-4.43%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	\$12.50	\$459	-33.86%
2	Bioventus	BVS	\$2.93	\$230	-25.82%
3	AxoGen	AXGN	\$4.85	\$208	-25.61%
4	ZimVie	ZIMV	\$9.67	\$257	-15.69%
5	Alphatec Holdings	ATEC	\$12.77	\$1,536	-15.15%
6	SINTX Technologies	SINT	\$0.83	\$3	-14.23%
7	Xtant Medical Hldgs	XTNT	\$1.04	\$134	-11.86%
8	Pacira Biosciences	PCRX	\$33.15	\$1,539	-11.32%
9	OrthoPediatrics Corp	KIDS	\$32.72	\$764	-10.84%
10	Integra LifeSciences	IART	\$38.56	\$3,139	-9.27%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Integra LifeSciences	IART	\$38.56	\$3,139	17.39
2	Johnson & Johnson	JNJ	\$160.50	\$385,438	18.55
3	Medtronic	MDT	\$80.27	\$106,802	18.95
4	Globus Medical	GMED	\$50.77	\$7,097	23.97
5	Zimmer Biomet	ZBH	\$116.85	\$24,417	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Pacira Biosciences	PCRX	\$33.15	\$1,539	66.69
2	Medacta	MOVE	\$133.72	\$2,674	51.13
3	Smith & Nephew	SNN	\$25.36	\$11,075	49.66
4	ConMed	CNMD	\$101.15	\$3,109	37.41
5	Stryker	SYK	\$285.28	\$108,343	33.63

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	\$25.36	\$11,075	-6.21
2	ConMed	CNMD	\$101.15	\$3,109	1.34
3	Medacta	MOVE	\$133.72	\$2,674	1.82
4	Globus Medical	GMED	\$50.77	\$7,097	1.96
5	Johnson & Johnson	JNJ	\$160.50	\$385,438	3.23

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Medtronic	MDT	\$80.27	\$106,802	5.46
2	Integra LifeSciences	IART	\$38.56	\$3,139	4.70
3	Pacira Biosciences	PCRX	\$33.15	\$1,539	3.70
4	Zimmer Biomet	ZBH	\$116.85	\$24,417	3.62
5	Stryker	SYK	\$285.28	\$108,343	3.34

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	\$0.70	\$3	0.06
2	ZimVie	ZIMV	\$9.67	\$257	0.28
3	Bioventus	BVS	\$2.93	\$230	0.45
4	Aurora Spine	ASG.V	\$0.28	\$18	0.92
5	Orthofix	OFIX	\$12.50	\$459	1.00

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SI-BONE, Inc	SIBN	\$21.15	\$850	7.99
2	Globus Medical	GMED	\$50.77	\$7,097	6.94
3	OrthoPediatrics Corp	KIDS	\$32.72	\$764	6.25
4	Medacta	MOVE	\$133.72	\$2,674	6.12
5	Stryker	SYK	\$285.28	\$108,343	5.87

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

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Robin Young | robin@ryortho.com



Centinel Spine, After 41 Years, Exits Fusion to Focus on Motion

BY ROBIN YOUNG

Centinel Spine®, LLC, named for the radiographic confirmation of a successful fusion anterior to an interbody device, “Sentinel Sign”, has sold its **STALIF**® and other fusion products business to Swiss-based Silony Medical International for an undisclosed amount.

The **STALIF** family of fusion products, which were developed by Centinel Spine’s predecessor firm, UK-based Surgicraft, founded in 1982, are based on the then revolutionary titanium Hartshill Horseshoe. When it was first commercialized in 1988, it was the first Stand-Alone/No Profile® anterior lumbar interbody fusion device in the world.

Surgicraft and later Centinel Spine, under the leadership of John Viscogliosi along with his brothers Anthony and Marc and the teams they developed, created generations of the market-leading Integrated Interbody™ technology products.

Branded as **STALIF** with improvements over the years, the technology stands on 35+ years of clinical history and more than 100,000 implantations worldwide.

"We are proud of the progress our Centinel Spine team accomplished in building and advancing our fusion business. The **STALIF** products and expertise moving to Silony Medical will be a valuable addition to their global business," said Centinel Spine CEO Steve Murray.



Centinel Spine®, LLC

"Silony Medical's strong focus on the development and manufacture of fusion implants and instruments will enable their business to expand and meet its potential in a focused environment."

"The **STALIF** portfolio and additional spinal fusion products Silony Medical is acquiring from Centinel Spine will be a welcome and strategic addition to our portfolio," said Silony Medical's CEO Constantin Schoen.

"These are proven and trusted devices with an established presence around the world. Combined with Silony's current portfolio, we extend our commitment to provide effective solutions for daily surgical practice."

"In addition to technology," added Schoen, "Silony will welcome a team of professionals from Centinel Spine whose expertise in the anterior fusion market advances

patient care every day. The Silony team is committed to successful long-term relationships, and we look forward to continuing to work with the established **STALIF** distributor and surgeon partners around the world."

Centinel Spine is selling all cervical and lumbar fusion products—including the **STALIF** technology platform and expects to close the transaction within 30-45 days from the announcement. Terms were not disclosed.

Who Is Silony Medical?

Silony Medical is the Swiss-based supplier of a wide variety of spinal implants and instruments. Its U.S. offices are in Doral, Florida. Silony's CEO, Constantin Schoen, is also managing director at the investment firm, Apollon SE, which is the Schoen family's investment holding company with €2b in assets under management.

The Schoen family owns the famous Schoen Klinik Gruppe, the largest family-run hospital group in Germany, which was founded in 1985. The Schoen Klinik has 30 locations in both Germany and England and treats around 300,000 patients each year.

In addition to Silony Medical, Apollon SE has also invested in three other suppliers of orthopedic and orthotic products—Orthopädietechnik München Harlaching, Orthopädietechnik Chiemgau in Vogtareuth and Orthopädietechnik Hamburg and Orthopädietechnik Neustadt.

Each investment, I imagine, is complimentary and synergistic with the Schoen Klinik as well as strong independent suppliers in their own right.

Into this broad-based organization, Centinel's **STALIF** and fusion family of technologies will, no doubt, contribute significantly.

Centinel Spine's Strategic Move to be the #1 Motion Preservation Supplier in Spine

Commenting on the sale of his company's fusion products to Silony, Centinel's CEO, Steve Murray said, "This divestiture allows Centinel Spine to focus exclusively on total disc replacement and expand our leadership in this rapidly growing market."

Centinel Spine's 2022 **prodisc**® TDR revenue approached \$45 million, a record for the company.

Today, Centinel Spine holds the #2 market share in cervical and lumbar

total disc arthroplasty in the U.S. but is #1 in worldwide lumbar total disc arthroplasty revenue.

The company's **prodisc** TDR business continues to accelerate in 2023 and grew 50% in the first half of the year—driven primarily by the September 2022 limited release of the new **prodisc** C Vivo and **prodisc** C SK cervical TDR system in the U.S. and strong global demand for Centinel's lumbar **prodisc** total disc arthroplasty.

Centinel's Back to the Future Moment


Centinel Spine began operations in 2008 through the merger-acquisition of Raymedica, LLC and Surgicraft, LTD.

Founded in 1990, Raymedica was a pioneer in disc motion technologies and


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brought to market a nucleus replacement technology called PDN—Prosthetic Disc Nucleus—which helped thousands of patients around the world to restore function.

Raymedica was founded by and named after a legendary surgeon and innovator, Charles Ray, M.D. Here is his **profile**.

Anthony Viscogliosi was the chairman of RayMedica in those days and he, along with his brothers Marc and John, pioneered the entire category of motion preservation. The brothers famously acquired the rights to another early motion preservation technology—**prodisc**—and despite nearly overwhelming odds—shepherded the technology through the FDA’s PMA process.

Spine Solutions, LLC, the company founded by the V-Brothers for **prodisc** was acquired by Synthes in 2003 for \$350 million. In 2006, Synthes launched **prodisc**. Since then second and third generation disc arthroplasty products have been approved by the FDA.

In 2012, Johnson & Johnson acquired Synthes and in 2018, sold **prodisc** back to the Viscogliosi brothers and Centinel Spine, a VB portfolio company, added **prodisc** to its line of spinal implant and instrumentation products.

Centinel invested heavily in the **prodisc**® franchise—which at the time it was acquired was already the most extensive cervical and lumbar motion-preserving reconstruction portfolio

available on the market. Today, **prodisc** is the only spine arthroplasty technology with multiple solutions for both cervical and lumbar anterior column reconstruction.

It is also the most studied and clinically proven TDR system across the globe, validated by over 540 published papers and 240,000 implantations worldwide.

Finally, **prodisc** is a three-time Spine Technology Award winner.

All in all, after 41 years and so many contributors, twists and turns, Centinel Spine returns to a singular focus—indeed, Tony, Marc, and John’s vision all those years ago—of making motion preservation a foundational part of surgical spine care. ♦

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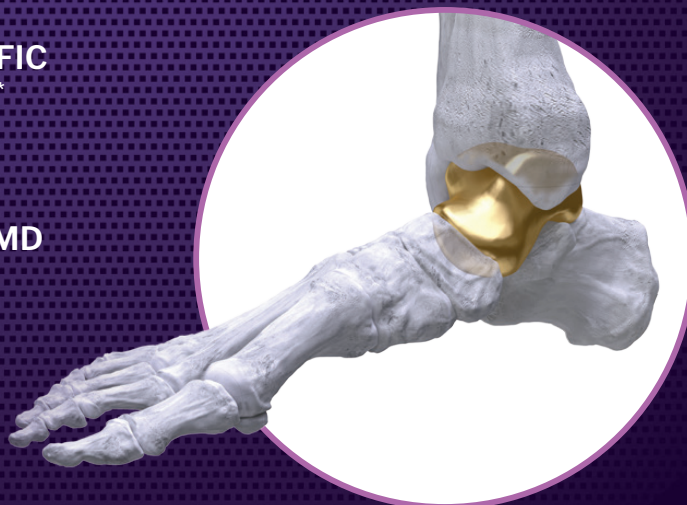
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How ‘Political’ Are Orthopedic Surgeons?

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

How political is your “average” hip and knee surgeon?

And, to what extent do they take advantage of opportunities to help craft governmental policies that influence their work, as well as the lives of patients?

A team from Rothman Orthopaedic Institute at Thomas Jefferson University, Maine Medical Partners, OrthoCarolina, and the American Association of Hip and Knee Surgeons (AAHKS) launched an effort to find answers to these questions.

Their research, “[Health Policy Views and Political Advocacy of Arthroplasty Surgeons: A Survey of the American Association of Hip and Knee Surgeons Members](#),” was published in the August 2023 edition of *The Journal of Arthroplasty*.

The OR and the Boardroom

Co-author P. Maxwell Courtney, M.D., division chief of adult reconstruction at the Rothman Orthopaedic Institute-Thomas Jefferson University explained to OTW, “We have been facing substantial headwinds in trying to preserve access for our joint replacement patients over the past few years. Hip and knee replacements are one of the most successful operations we perform in medicine and provide great value to our patients. With many recent policy changes, we as surgeons cannot just focus on patient care anymore and need to be advocates educating the public and our elected officials on the issues we face.”



Source: Shutterstock

The researchers distributed a 22-question email survey on multiple occasions to all 3,638 U.S. members of AAHKS who were in practice or training in 2022, ultimately obtaining 311 responses.

The survey was divided into three parts:

- 1) Demographics—membership level, political affiliation, surgical experience, and practice setting
- 2) Policy views including perceptions of contemporary policy issues, mispriced procedure codes, awareness of recent changes to

the fee schedule for arthroplasty procedures, and experience with bundled payment systems.

- 3) Advocacy participation including political donations, current advocacy efforts, and barriers to participation.

The team found that 18% of respondents had begun practicing within the last 5 years and 38% had more than 20 years of practice.

Their political affiliations were:

- 1) Republicans (40%),

- 2) Independents (37%), and
- 3) Democrats (21%).

The top concerns were:

- 1) preserving physician reimbursement and equitable fee schedule representation (95%),
- 2) the burden of prior authorization (53%),
- 3) the impact of Center of Medicare and Medicaid Services regulations (39%), and
- 4) medical liability and tort reform (39%).

The top benefits from participating as advocates for their profession were:

- 1) maintaining appropriate physician reimbursement (44%) and
- 2) advocating for patients (37%)

And what do most orthopedic surgeons want? Survey says: (81%) more time on pre-surgery optimization now than 10 years ago.

What was the most common impediment to advocacy participation? Lack of time (77%).

“This study showed that many AAHKS members are informed and actively engaged in the political process,” stated Dr. Courtney to *OTW*.

“Regardless of personal political party affiliation, we continue to advocate for non-partisan causes. Although inflation is up 20% in the last four years,

Medicare reimbursements for total joint replacements have dropped substantially. Insurance companies often require a prior authorization process to approve a test or a procedure, burdening our clinical staff, requiring more time on the phone for the physicians, and causing frustration in the delay of care for our patients.”

“Medical liability continues to be an issue in several states, with us in Pennsylvania fighting ‘venue shopping,’ where a plaintiff’s attorney can file a lawsuit in a more litigious county anywhere in the state, not just where the surgeon practices. We hope our study can prompt other subspecialty societies to continue to engage its members to take an active role in the political process to advocate for their patients.” ♦



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AAOS and AMA Oppose Proposed CMS Physician Pay Cuts

BY KIM DELMONICO



Source: American Medical Association, Centers for Medicare & Medicaid Services and American Academy of Orthopaedic Surgeons

The American Medical Association (AMA) and the American Academy of Orthopaedic Surgeons (AAOS) are actively opposing CMS's proposed changes in the physician payment formula. AMA made its position known in a [comment letter](#) it sent to the Centers for Medicare & Medicaid Services (CMS). Almost immediately after the AMA's letter, [AAOS](#) followed suit with its own sharp critique of CMS's proposal.

Both comment letters were drafted in response to a proposed rule issued by CMS last month: "[Medicare and Medicaid Programs: CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program.](#)" The

proposed rule addresses a number of changes. Notably, changes to the physician fee schedule.

In the AMA's letter, the physician society, largest in the United States, pointed at CMS's "ongoing conversion factor reductions, specifically the proposed 3.36 percent reduction in the 2024 Medicare conversion factor (CF), with corresponding reductions in anesthesia CF rates." It expressed concern about the potential implications of the proposed cuts for both physicians and patients. It pointed out that the proposed payment reductions are attributable to two factors: a 1.25% reduction from a temporary legislative update and a "negative budget neutrality adjustment linked to the introduction of an office visit add-on code."

In an accompanying press release, AMA President Jesse M. Ehrenfeld,

M.D., MPH said, "With higher costs for everything associated with practicing medicine, another year of Medicare payment cuts jeopardizes patient access and imperils the physician practices on which so many seniors rely."

Dr. Ehrenfeld continued, "These cuts are unsustainable and unconscionable."

AAOS President, Kevin Bozic, M.D., MBA, FAAOS said in his letter to CMS administrator Chiquita Brooks-LaSure, "Our ability to deliver high quality musculoskeletal care is hampered by inflationary pressures on practice expense."

"By some estimates, the MPFS conversion factor would have been double the amount being currently proposed, had it kept up with inflation." What makes these changes so disappointing is that, as Dr. Bozic wrote in his letter, "With

inflation soaring to 40-year highs this year, on-going and scheduled statutory payment cuts, and many physician practices still dealing with pandemic-related financial and staffing issues, the current proposal from CMS undermines the long-term sustainability of physician practices while threatening patient access to physicians participating in Medicare.”

Both societies, AAOS and AMA, provided additional data to support their positions. From 2001 to 2023, said both societies, “the cost of operating a medical practice has surged by 47%, while physician payment rates have increased by only 9%. Additionally, when adjusted for inflation, “Medicare physician payment rates have plummeted by 26%.” This is “projected to worsen next year.”

Both letters also addressed other issues that will potentially affect physicians and group practices in the coming year. Notably, the AMA indicated the potential that “more physicians and group practices will be hit with a MIPS [Merit-based Incentive Payment System] penalty in 2024 based on the newly released 2022 performance period feedback.” The penalties have the potential, according to the AMA, to reduce Medicare payment by as much as 9%.

The comment letters are just one of many steps that both AAOS and AMA are taking to encourage Medicare physician payment reform.

For its part, at the Annual Meeting physicians, the AMA “called for a multi-pronged campaign to overhaul the out-

dated Medicare payment system, saying that patient access and survival of practices are at risk.” The AMA has also worked in conjunction with a number of other organizations to provide guidance for Medicare physician payment reform, entitled “[Characteristics of a Rational Medicare Payment System](#).”

In its recent communication to CMS, AAOS’s President Kevin J. Bozic said, “we urge CMS to support a statutory fix that provides an annual inflationary update for physicians, akin to all other providers covered by the Medicare payment system. Orthopaedic surgeons have been at the forefront of the transition to value-based care, and we are eager to work together to improve upon existing value-based payment and delivery models in the Medicare program.” ♦

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510(k) Clearance for Pediatric Tibial Intramedullary Fixation Rod

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to a pediatric tibial intramedullary fixation rod.

According to the 510(k) summary document, the device is “intended as a temporary implant for alignment, stabilization and fixation of tibias that have been surgically prepared (osteotomy) for correction of deformities or have sustained fracture due to trauma or disease.” The “patient population is pediatric, including child and adolescent subgroups, and small-stature adults—such as patient with small



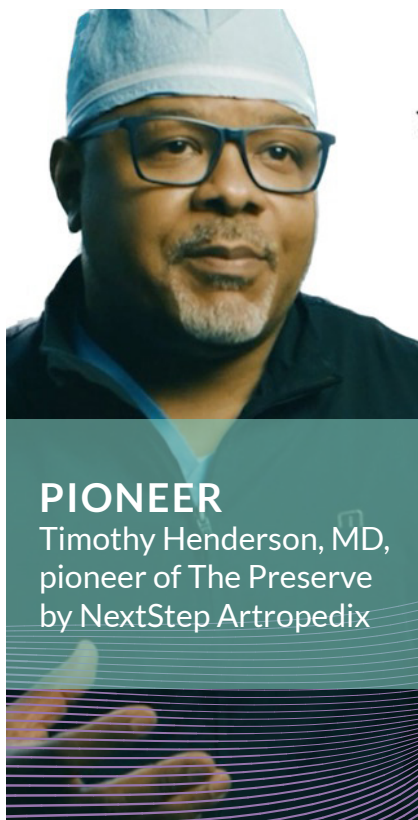
Courtesy of OrthoPediatrics Corp.

intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases.” Additionally, “nail lengths greater than 400mm are for skeletally mature patients.”

ing in diameters from 7mm-12mm, and includes specialized instrumentation to facilitate multiple surgical techniques.” The system was created for “children’s anatomy and growing patients.”

According to the company, the system “features rigid cannulated nails, rang-

Warsaw, Indiana-based OrthoPediatrics Corp. submitted the device for 510(k)



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Timothy Henderson, MD,
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clearance. OrthoPediatics focuses on developing pediatric orthopedic implants and instruments. Its device is called the Pediatric Nailing Platform | Tibia.

In order to qualify for the shorter and earlier 510(k) clearance the device must be substantially equivalent to a predicate device. The primary predicate device provided in the 510(k) summary document is the Simple Locking Intramedullary (SLIM) System by Pega Medical Inc. which is now owned by OrthoPediatics. The secondary predicate devices include the GAP Endo-Exo Medullary System by Pega Medical Inc. and the Affixus Tibial Nailing System by Biomet Incorporated (now owned by Zimmer Biomet).

OrthoPediatics President of Trauma and Deformity Correction Joe Hauser

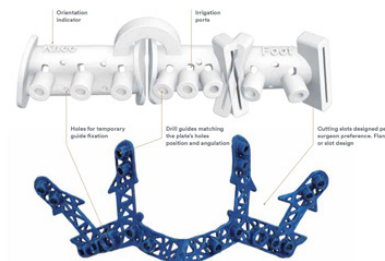
said, “We are pleased with the FDA 510(k) clearance for our new PNP Tibia System, which allows physicians to better treat children with implants and instruments that are made for their unique anatomy and musculoskeletal conditions. Our engineering team developed this first of its kind system in close collaboration with a group of renown surgeons to address the most common challenges they face in tibial trauma and deformity cases.”

Hauser continued, “The PNP Tibia System expands our Pediatric Nailing Platform, which has quickly become the market leader and is our largest trauma product. We are excited by its growth prospects and to bring yet another system to market in our effort to surround our surgeon customers with everything they need to help kids.” — KD

FDA’s Draft Guidance for Patient-Matched Ortho Implant Guides

Earlier this summer the U.S. Food and Drug Administration (FDA) issued [draft guidance](#) regarding patient-matched guides to orthopedic implants.

In the draft guidance, the FDA “provides recommendations regarding information that should be included in regula-



Courtesy of DePuy Synthes

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tory submissions for patient-matched guides to orthopedic implants.” It also provides “recommendations that manufacturers should consider when developing their design process for these device types.”

Draft guidance, when finalized, represents the current thinking of the FDA. It does not establish rights and is not binding.

As discussed in the draft guidance, patient-matched guides are distinct from custom devices. Here, patient-matched guides are “designed to implement, in part or in whole, the pre-operative plan concurred upon by the patient’s healthcare professional.” The FDA limits the draft guidance to patient-matched guides intended for use with “legally marketed orthopedic implant systems that include recommended alignment parameters relative to rigid anatomical

structures that can be identified on pre-operative imaging.”

The FDA provides guidance for the patient-matched guides indications for use. The FDA provides a list of the indications for use of an orthopedic patient-matched guide in the draft guidance.

The FDA also provides guidance regarding device description, indicating that the device description “should encompass the patient-matched guide design as well as the design process and surgical use.” The FDA details the following which should be included in a complete device description:

- Patient-matched guide description
- General design process description
- Patient image acquisition description

- Image quality control, segmentation, and anatomical definitions description
- Pre-operative planning and healthcare professional concurrence description
- Guide design and patient-matched features definition description
- Guide construction description
- Surgical technique description

The FDA also touched on software used in the development of patient-matched guides. It refers manufacturers to existing software guidance, “[Content of Pre-market Submissions for Device Software Functions.](#)”

The FDA also discusses when modifications may necessitate a new 510(k) sub-



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mission. It details a non-exhaustive list that includes four changes as requiring a new 510(k) submission and refers readers to additional FDA guidance for more details including the following: [“Deciding When to Submit a 510\(k\) for a Change to an Existing Device”](#) and [“Deciding When to Submit a 510\(k\) for a Software Change to an Existing Device.”](#) — KD

EXTREMITIES

New Shoulder System Features Smallest Baseplate Yet

Anika Therapeutics, Inc. announced the full market release of their novel RevoMotion™ Reverse Shoulder Arthroplasty System which, among other features, brings to the surgeon a 23mm diameter baseplate, the smallest threaded baseplate on the market.

The importance of a smaller profile baseplate was highlighted at the recent 2023 Orthopaedic Summit Evolving Technologies (OSET) meeting by Christopher Baker, M.D., Florida Orthopaedic Institute, Tampa, Florida who said, “A 23mm diameter baseplate, the smallest threaded baseplate on the market, allows me the potential to save glenoid bone-stock and provides flexibility in positioning, so that I can treat a variety of glenoid morphologies.”

Furthermore, said Dr. Baker, “With short term follow-up we are seeing tremendous satisfaction from our patients and improving pain and function.”

Anika, a Global Joint Preservation Company

Bedford, Massachusetts-based Anika Therapeutics, which built its reputation

among orthopedic surgeons as an hyaluronic acid (HA) knee injection company, has expanded significantly under President and CEO Cheryl Blanchard and now offers, for example, a full range of innovative shoulder arthroplasty, bone conserving solutions.

In addition to RevoMotion, Anika is providing extremity surgeons with a full continuum of rotator cuff disease treatments including the recently launched X-Twist™ Fixation System and newly cleared Integrity™ regenerative hyaluronic acid-based patch system launching in Q1-2024

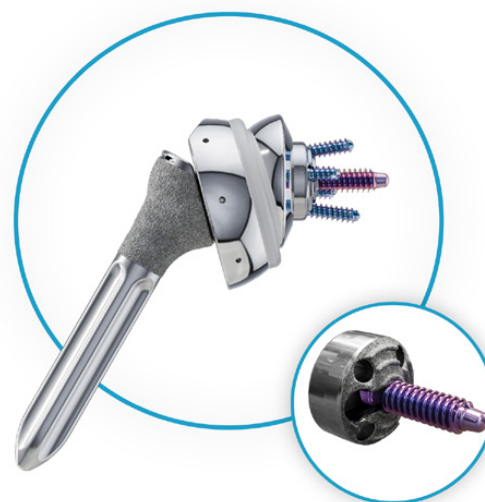
Blanchard said this at the recent OSET meeting: “We’re excited to participate in this year’s OSET Annual Meeting, where we are showcasing our breakthrough new products focused on early intervention orthopedics, including the launch of our RevoMotion Reverse Shoulder Arthroplasty System, designed specifically to address clinical needs through a truly bone preserving design with simple and efficient instrumentation.”

In addition, said Blanchard, “We are also previewing our recently cleared Integrity regenerative HA-based rotator cuff patch system, which is uniquely strong, versatile, and easy-to-use. Integrity has an innovative delivery and fixation system and has greater regenerative capacity compared to first generation collagen patches.”

RevoMotion

According to Anika, the key features and benefits of RevoMotion are:

- Industry’s smallest diameter threaded glenoid baseplate in order to better preserve bone, provide flexibility in positioning and maximizing fixation of the glenoid components, all while achieving substantial fixation via a central compression screw.
- Mid-lay Humeral Implant: Partially in-lay and partially on-lay, with seven humeral tray sizes which provide a more precise fit and is designed to optimize range of motion and reduce risk of scapular notching. The humeral tray and bone preparation are designed to decrease stress shielding on the proximal humerus with forces evenly distributed across entire proximal humerus.
- Preserve bone and personalize to the patient. The system’s bone preserving glenoid and humeral designs provide patient personalization by way of numerous humeral tray offerings which match the native anatomy. This



RevoMotion™ Reverse Shoulder Arthroplasty System
Source: Anika Therapeutics, Inc.

approach is similar to Anika's other implant system designs in the ArthroSurface Joint Solutions portfolio including the flagship OVOMotion® with Inlay Glenoid Total Shoulder Arthroplasty System.

- More surgeon and facility efficiency. With two streamlined instrument trays, RevoMotion optimizes surgeon and facility efficiency. The consolidated instrumentation is both Ambulatory Surgery Center (ASC) and hospital friendly. Smaller back table footprint, reduced sterile reprocessing and, compared with more complex designs currently on the market, more affordable.

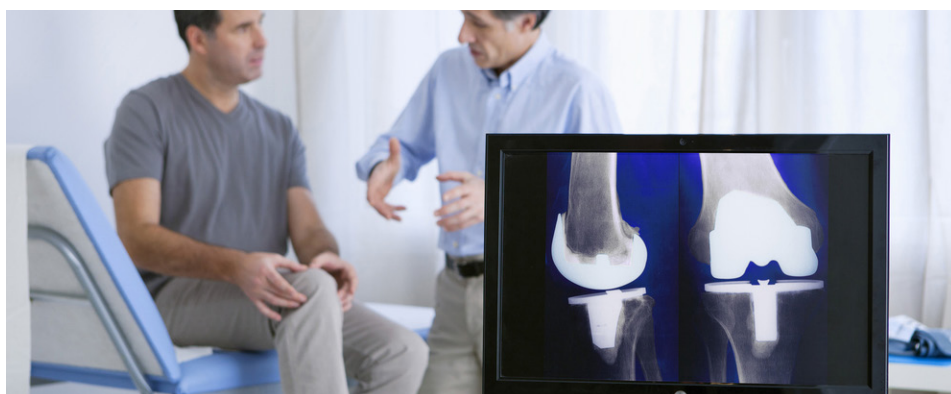
For more information: www.anika.com
— RRY

SPORTS MEDICINE

How Fast Can Young TKA Patients Get Back to Sports?

How fast can younger total knee Arthroplasty (TKA) patients get back to work or play?

That's the question a team of Cleveland Clinic and Case Western Reserve researchers tried to answer with a systematic review of the literature. The team was hoping to quantify to determine rates, timelines, and prognostic factors which can determine how fast young TKA patients return to work and / or return to sports. Their work, "[Return to Sports and Return to Work After Total Knee Arthroplasty: A Sys-](#)



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[thematic Review and Meta-Analysis.](#)” was published in *The Journal of Bone and Joint Surgery* on July 27, 2023.

The Cleveland Clinic and Case Western Reserve University School of Medicine research team reviewed 44 studies with 9,113 patients who’d been treated with a primary TKA. Indeed, while different aspects of TKA patient return to work or play have been reviewed before, according to co-author Nicolas Piuzzi, M.D., “This is the most up-to-date and comprehensive study to look at both return to work and return to sports in patients undergoing TKA.”

Dr. Piuzzi, who is co-director of the Musculoskeletal Research Cen-

ter at Cleveland Clinic, added, “The increasing utilization of TKAs, particularly among younger patients, and the significance of resuming activities like employment and sports after the procedure, have sparked our interest in this subject. Recognizing the growing importance of return to work and return to sports after TKA for patient satisfaction prompted us to delve into better understanding the implications and outcomes of TKAs in these contexts.”

Considering all studies, the team found the return-to-work rate to be 65% (rates varied from 10% to 98%). The mean time to return to work was 12.9

weeks. The investigators determined that increased age was associated with lower return-to-work rates.

The overall return-to-sports rate was 82% (ranging from 36% to 100%). The mean time to return to sports was 20.1 weeks.

Breaking things down further, the researchers categorized the sports into high-intensity (hiking, running, and tennis) and low-intensity (golf, walking, swimming, and cycling). They found that return-to-sports ranged from 43% to 98%, with a pooled proportion of 76% for low-intensity sports, and from 0% to 55% for high-intensity sports, with a pooled proportion of 35%.

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Specifically, walking and swimming had the highest pooled incidences with 81% and 71%, respectively, whereas running and tennis had the lowest incidences—14% and 20%.

“The comprehensive analysis of factors affecting return-to-work and return-to-sports underlines the complexity of this topic,” said Dr. PiuZZi to *OTW*. “This awareness is crucial for managing patient expectations and providing tailored counseling, considering the intricate variables influencing post-TKA return to activity and expected timelines.”

Dr. PiuZZi also addressed the issue of patient expectations and told *OTW*, “We place emphasis on the standardized and consistent integration of this topic [return to work or play] into discussions with all patients scheduled for elective TKA. Our suggestion is rooted in the understanding that a proactive approach to addressing return-to-work and return-to-sports aspirations can lead to enhanced patient satisfaction. This practice would ensure that patients are well-informed, allowing them to actively participate in decisions and planning regarding their recovery journey.” — *EH*

One such non-profit organization is RESTORE WORLDWIDE, INC., which was founded 15 years ago by Dr. Michael K. Obeng, an award-winning Beverly Hills plastic surgeon, humanitarian, philanthropist, and global health strategist.

RESTORE WORLDWIDE provides free reconstructive surgeries and related medical services to children and adults with disfiguring deformities—whether present at birth or caused by accidents or diseases and involving head and neck region, trunk, breasts, extremities, and genitalia.

As part of its mission, RESTORE also educates and trains local medical professionals on the latest techniques and safety measures in plastic and reconstructive surgery, effecting change long after the RESTORE team leaves these communities.

Mission to Cameroon’s Capital, Yaoundé

Earlier this year, Dr. Obeng and his colleagues, including our friend and Los Angeles-based spine surgeon, Gil Tepper, M.D., completed their 24th mission (Dr. Tepper’s first). The team met with patients over the course of a week and carried out 315 vital medical oper-

ations, making this the largest mission for RESTORE.

It was RESTORE’s second humanitarian trip to Yaoundé, Cameroon, with its biggest-ever team of 40 healthcare personnel.

The mission trip was a collaborative effort between doctors from the United States, France, Germany, Senegal, Mali, and the United Kingdom, and was fully sponsored by a philanthropist and entrepreneur Eran Moas, founder of Avi Sivan Abraham Foundation (ASAF) Cameroon.

The team worked in two shifts (from 7am to 4am). Their patients were people who otherwise had limited or no access to medical help because of economic factors or the complex nature of their condition and lack of local expertise.

The team performed:

- Cleft lip and palate repair
- Craniofacial surgery
- Tumor resection and reconstruction
- Burn reconstruction

PEOPLE

One Surgeon’s Experience Volunteering Internationally

There are several terrific organizations that arrange trips all over the world to provide free musculoskeletal care to people who do not have ready (or even remote) access to quality healthcare.



Ben Djoubairou, M.D., Gil Tepper, M.D. and Dr. Njofang Teto Poulenc / Courtesy of Gil Tepper, M.D.

- Breast surgery including mastectomies and reconstruction
- Hand, foot & extremity surgery
- Excision and debulking of tumors
- Intersex surgery/gender re-affirmation surgery
- Spine/orthopedic surgery
- Urology/gynecology reconstruction
- Auditory diagnostics and care



Courtesy of RESTORE WORLDWIDE, Inc.

This was Los Angeles-based surgeon, Gil Tepper's, first time participating in such a mission trip.

"I was looking for a way to give something back, to do something new and out of my comfort zone," said Dr. Tepper to OTW.

When Dr. Tepper was a resident, he circulated through the trauma department and learned how to "work with what you had and make the most of the equipment and resources at your disposal to solve the problem in front of you."

Dr. Tepper knew Dr. Obeng already. They both have practices in the Los

Angeles area and Dr. Tepper had assisted Dr. Obeng in reconstructive plastic surgery cases. Over the years Dr. Obeng had told Dr. Tepper stories of traveling to Africa to treat underprivileged patients and he explained that the mission needed surgeons with Dr. Tepper's level of experience.

As many surgeons have related to OTW over the years, the notion of donating time and skill to help underprivileged patients, speaks to the very reasons most physicians choose this profession.

Dr. Tepper liked what he heard and, with his private practice on hiatus, he joined the RESTORE team for their ambitious trip to Cameroon.

In Country

In Yaoundé, Dr. Tepper teamed up with local Cameroonian neurosurgeon, Ben

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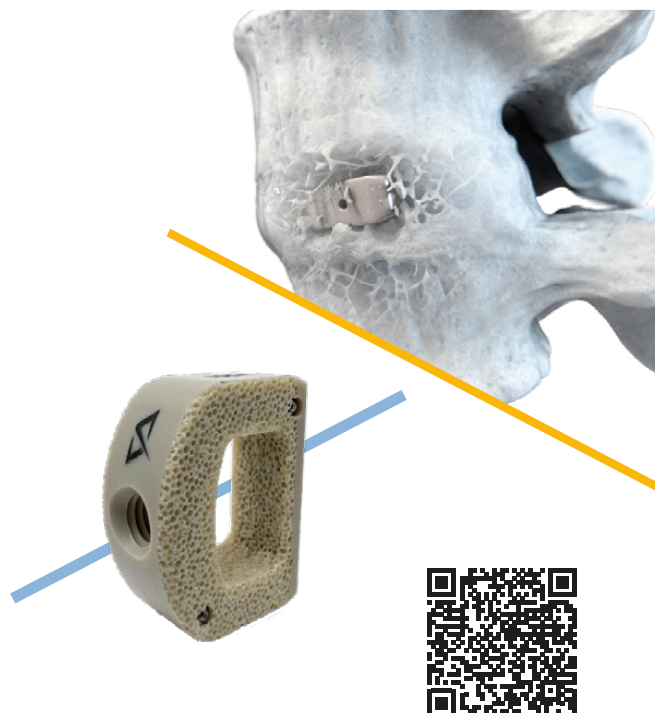
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Djoubairou, M.D., who practices at the Yaoundé Military Hospital where RESTORE does most of their work.

Dr. Djoubairou began preparing for the RESTORE team two weeks before Dr. Tepper arrived. He reviewed patient charts and diagnostic tests and X-rays. Over the ensuing week, Tepper and Dr. Djoubairou and local staff worked their way through simple spinal decompressions, to instrumented procedures, screws and rods, and wrapped up the week performing complex deformity correction cases.

“The waiting room at the hospital was always full, very crowded. I had to adjust to protocols unique to Cameroon and which we don’t have to use in the United States—even when it came to the weather. When it rains in Africa, it really RAINS,” recalls Tepper.

“We actually had to move our staff and patient to a different, less leaky room because of the rain.”

To be sure, the Yaoundé Military Hospital is a modern facility and quite up to date. The RESTORE team was an extra set of 80, well trained, experienced hands which blended for a week with the local staff.

“Patients came from many miles around Yaoundé. When local RESTORE organizers sent word out that



Gil Tepper, M.D. (left) and Mbele Messanga Innocent Ghislain, M.D., in Surgery / Courtesy of Gil Tepper, M.D.

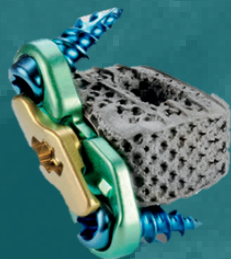


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an international team of top-notch surgeons and physicians was coming to town, patients came, many from very long distances.”

The arriving patients, Dr. Tepper told *OTW*, waited in hallways, stairwells and even lined up outside the hospital wrapping around the building. Many waited hours to hear their name called—after which they were evaluated and placed in the diagnostic and treatment queue.

Dr. Tepper found that, like all physicians who volunteer in programs like RESTORE, the range of cases was extraordinary. One patient might need plastic surgery, the next bone grafting, then a spine decompression case, the end the day with a maxillofacial case.

“What was interesting for me was the fact that I was able to partici-

pate in other surgeries with other specialists between my spine cases,” he said. These cases included ones where he harvested iliac bone graft, performed hand surgeries with a plastic surgeon or a deformity correction with a foot and ankle surgeon, remembers Tepper.

Out of Your Comfort Zone

Tepper was in a new environment with its own unique set of rules—which he needed to adapt to, not the other way around.

Sharing ideas and techniques was fine, but, he was also there to learn, not instruct. “It’s a time to check your ego at the door and, as long as we are safe, and pick the proper patients we’ll be ok. It takes creativity, flexibility to get the work done,” recalls Tepper. “If there is an instrument you would like to have

and it’s not available, you need to use what you have in front of you.”

And being out of his Los Angeles comfort zone was one of the aspects of the mission he liked best. “The fact that you are doing these cases with what you have and making a difference in these patients’ lives makes you wonder if all the options we have in our lives are really necessary?”

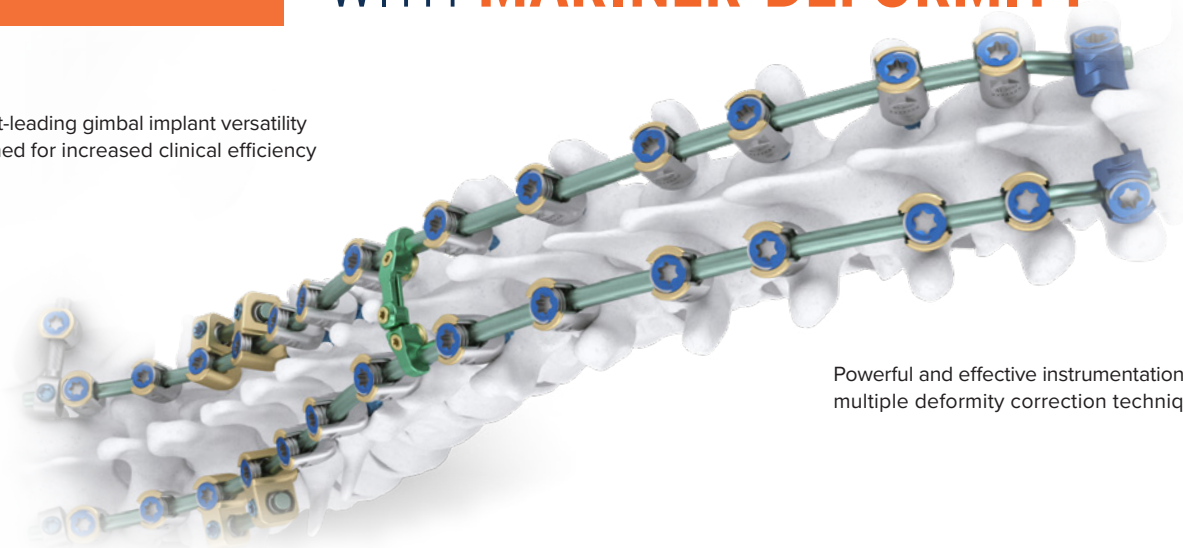
It’s Not About You, It’s About the Work

The entire RESTORE team are volunteers. They get on the planes, bring whatever they can in terms of supplies, skill, and experience and then, not knowing precisely what they will be confronting in terms of patients and infrastructure, dive in. Go to work. Hour after hour, day after day, a mere member of a multi-cultural team.



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Want to participate in a similar program?

We hope you will.

Dr. Tepper has a couple suggestions.

- First, find a partner surgeon who is already there or has experience in the hospital you will be going to. Together you can review patient records and pre-plan not only your surgeries but also the surgical/clinic schedule.
- Be resourceful.
- Harken back to your training when you were a resident and had to make do with what you had.

Already Dr. Tepper is planning his next mission—this time to Ghana in November. The lessons he learned

from the RESTORE mission to Cameroon, he plans to apply to his trip to Ghana—specifically, spend more time with the local staff, learn their protocols for reviewing patient records and pre-screening. Doing that, he believes, will give him a better idea of where in the mission the patients fit. For example, could this patient be treated in the clinic alone or do they need to be taken to surgery as soon as possible? If they need a surgical intervention, what implants/instruments are required?

For the Ghana mission, industry will be helping more with equipment. Additionally, Tepper plans to ship what he needs directly to the hospital. This has its own logistical hurdles to clear, but it will make a huge difference in his travel plans and allow him to treat more patients.

Tepper also recruited another spine surgeon to accompany him.

“RESTORE”, incidentally, stands for:

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—JC

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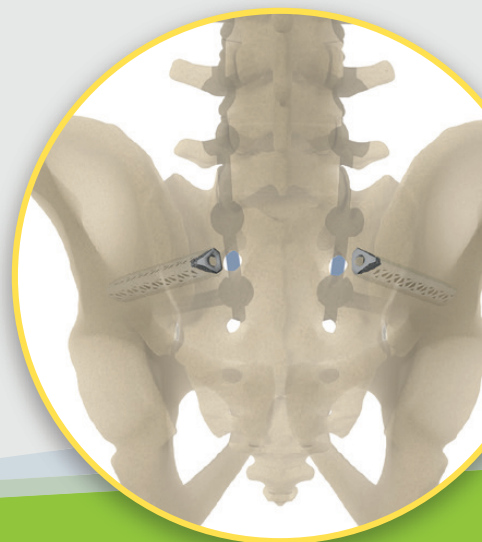
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REMEMBRANCES

Foot & Ankle Surgeon Ronald J. Bruscia Dies at 75

Ronald J. Bruscia, DPM, a foot and ankle surgeon in Katy, Texas, passed away on February 4, 2023, at the age of 75. He cared for podiatric patients in Katy and the greater Houston area for more than 30 years.

Bruscia received his Doctor of Podiatric Medicine from the Ohio College of Podiatric Medicine in Cleveland, Ohio. He then completed his foot and ankle surgical training through the Harris County Podiatric Residency Program in Houston, Texas. He was a Fellow of the American College of Sports Medicine and was board certified through the American Board of Multiple Specialties in Podiatry.



Ronald J. Bruscia, DPM
Courtesy of Schmidt
Funeral Home

He completed his undergraduate degree at State University of New York at Buffalo.

He was a member of the U.S. Army Reserves and received an Honorable Discharge in July 1970. Bruscia married Kathleen Jane Burke on May 29, 1992, in Worcester, Massachusetts.

Giving back was very important to Bruscia. He served as a board member at the Katy YMCA and was the director of the annual YMCA Turkey Dash race for many years. He also loved to partici-

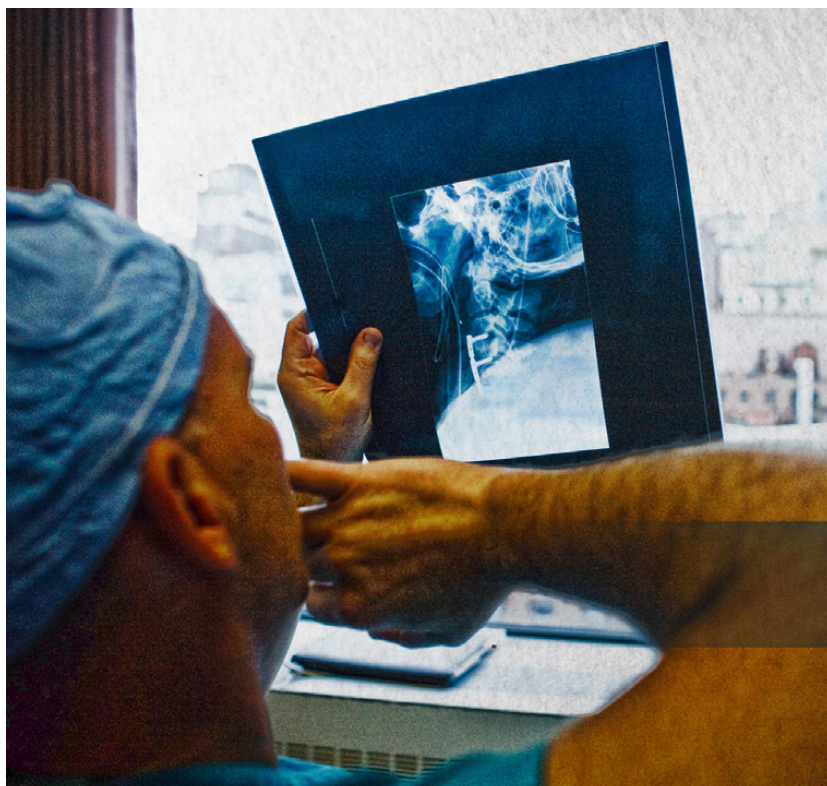
Bruscia was born on April 23, 1947, in Buffalo, New York, to Ronald Sr. and Frances Wozniak Bruscia. He graduated from Bishop Timon High School in Buffalo, New York, and completed his

pate in charity golf events in the greater Houston area.

Always very active, he enjoyed swimming and running and completed 18 marathons and triathlons including the Boston Marathon. He also competed in inline skating races across the country. He also loved cars and his Astros.

He is survived by his wife, Kathy Bruscia; and children, Ronald Bruscia, III and Rosann Sear of Austin, Ethan Bruscia, Austin Bruscia and Grace Bruscia of Katy and Hannah Bruscia of Arlington, Texas. He also leaves behind his grandchildren, Giada Sear of Austin, Alana Bruscia of Katy and another grandchild due this spring; as well as his sister, Janice Morris of Katy; nephews, Kris Morris of Houston and Jon Morris of Austin.

Bruscia was preceded in death by his parents, Ronald James Bruscia, Sr. and Frances Wozniak Bruscia. — TR



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