

# Orthopedics • This Week

## week in review

**05 Midwest TKR—Where’s the Real Bargain?** ♦ Midwest facilities charge the lowest average prices for total knee replacements (TKR) in the entire U.S. But are all Midwest hospitals created equal? Read on to find out just how much the “bargain” can vary.

**11 On Message: Media Training for Orthopedists** ♦ Whether you are leading an orthopedic society, want to grow your practice, or are otherwise called upon to deliver a media message, knowing what to say and what to avoid is an art form that can be perfected.

**16 Fusion ICD Codes to Change** ♦ CMS is considering revisions to its spine fusion procedure ICD codes. Those codes are the “devil in the detail” of reimbursement. CMS hasn’t heard from the little guys, says an industry consultant. If your technology involves words like DLIF, XLIF, AxialIF, read on and submit your comments to CMS by November 20.



## the picture of success

**28 Dr. Bernard Stulberg** ♦ The former Chair of the AAOS Committee on Biomedical Engineering, Dr. Bernard Stulberg had the first medical practice in the U.S. that embraced the tenets of customer-focused and transparent health care, and became certified to ISO9001.



## breaking news

**19 Kyphon Whistleblowers Strike Again**

Antibodies May Worsen **Spinal Cord Damage**

**Medicrea** Launches New Product and Study

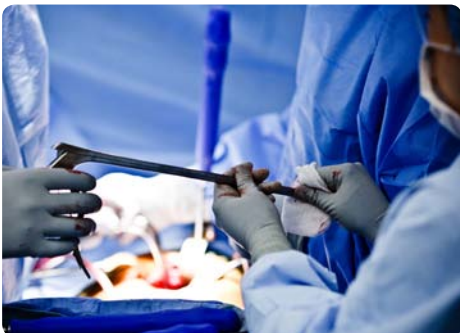
**Custom Spine** Makes Herrington Sales Chief

FDA Seeks Internet Promotion Input

**Alpha Orthotics:** New Foot Brace in the U.S.

Prosthetic Leg Safety

**For all the news that is Ortho, read on.**





## Reserve your seats now for the gala banquet!

*November 9, 2009 • The Palace Hotel • San Francisco*

All of the spine technology submissions have been received, and seats for the Spine Technology Awards and Gala Banquet are going fast.

These awards are the first of their kind and are designed to honor the best spine products, engineering teams and inventors of 2009. Don't miss this unique and important night when 100 attending spine surgeons will vote on entries in eight categories:

- Device Technologies for Cervical Care
- Lumbar Care
- Motion Preservation of the Spine
- Minimally Invasive Care
- Biomaterials
- Diagnostics and Imaging
- Pain Management
- Regenerative Technologies

**Each company or individual that submits products for evaluation will be recognized by *Orthopedics This Week* at the podium during the awards ceremony.**

The 24 finalists and the first place, second place and third place **awards in each category will be determined by real-time surgeon votes at the November 9 event.** The engineers/inventors for the top three products in each of the eight categories will be invited to the podium to describe their invention. The top three products in each category will receive crystal awards at the ceremony.

***Reserve your seats today—the number of spots remaining is extremely limited!***

*Click here* to print a reservation form and obtain more information, or contact Tom Bishow at [tom@ryortho.com](mailto:tom@ryortho.com) or Lisa Carpenter at [lisa@ryortho.com](mailto:lisa@ryortho.com).



# Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**This Week:** There was a decidedly small cap bump last week as buyers stepped up interest in Exactech, Alphatec and Orthofix. Big ortho declined—and the standard deviation between specific large ortho stocks narrowed—buyers are not evaluating individual large cap ortho companies at the moment. Just the sector.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Zimmer	29.31	11.38%	Buyers are increasingly interested in Big Blue Z. Why not? Great franchise, 29% profit margins, low valuation.
2	4	Orthofix	7.65%	11.00	Nice jump this past week on no new announcements. PSR less than 1.0, 17x earnings. Rising cash flows.
3	3	Smith & Nephew	20.95	3.96	5th lowest future P/E—which means that Wall Street has high growth expectations for the Memphis boys in this British company.
4	1	Stryker	23.28	6.16	Hate to downgrade SYK but near term the buying interest is on autopilot. Catalyst to watch for: hospital buying interest.
5	10	Exactech	12.87	5.86	Consensus estimate is 20% earnings growth on 4% sales growth. All we know, the Petty's have a record of growing 2x industry rate.
6	6	ArthroCare	16.87	16.96	ArthroCare is marching to a totally different drummer. Fundamentals? A select few know the numbers. Are they the buyers?
7	9	Medtronic	31.37	(4.40)	MDT now trading at valuations more normally associated with supermarket wholesalers. Up two spots.
8	5	CONMED	8.28	4.11	Just a stream of negative news these past six months. CNMD is due for favorable announcement in the coming six months.
9	7	Alphatec	(8.51)	2.97	Since CEO Kuyper arrived, ATEC has really turned operations around. Street is expecting breakeven Ops in 4Q.
10	8	Integra LifeSciences	12.32	(1.90)	Valuation is pretty reasonable, but not a blue-light special. If margins were higher, buyers would be more excited.

## Robin Young's Orthopedic Universe

### Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 I Flow Corp	IFLO	\$12.08	\$295	42.0%
2 Capstone Therapeutics	CAPS	\$0.82	\$33	22.4%
3 ArthroCare	ARTC	\$20.00	\$533	17.0%
4 Zimmer Holdings	ZMH	\$51.50	\$11,040	11.4%
5 Orthofix	OFIX	\$29.46	\$506	11.0%
6 Kensey Nash	KNSY	\$28.28	\$314	10.9%
7 Mako Surgical	MAKO	\$8.64	\$217	8.1%
8 Osteotech	OSTE	\$4.26	\$77	6.5%
9 Stryker	SYK	\$43.93	\$17,460	6.2%
10 Exactech	EXAC	\$15.36	\$196	5.9%

### Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Regen Biologics	RGBO.OB	\$0.75	\$7	-62.3%
2 RTI Biologics Inc	RTIX	\$3.85	\$209	-12.3%
3 Medtronic	MDT	\$36.46	\$40,350	-4.4%
4 Symmetry Medical	SMA	\$9.86	\$353	-4.3%
5 Orthovita	VITA	\$4.07	\$311	-2.9%
6 Integra LifeSciences	IART	\$32.61	\$927	-1.9%
7 Synthes	SYST.VX	\$115.99	\$13,765	-0.6%
8 NuVasive	NUVA	\$39.93	\$1,500	-0.2%
9 CryoLife	CRY	\$7.41	\$210	-0.1%
10 Johnson & Johnson	JNJ	\$59.73	\$164,600	-0.1%

### Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Symmetry Medical	SMA	\$9.86	\$353	8.99
2 ArthroCare	ARTC	\$20.00	\$533	11.75
3 Medtronic	MDT	\$36.46	\$40,350	12.12
4 Zimmer Holdings	ZMH	\$51.50	\$11,040	12.56
5 Johnson & Johnson	JNJ	\$59.73	\$164,600	13.24

### Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 I Flow Corp	IFLO	\$12.08	\$295	115.94
2 Smith & Nephew	SNN	\$44.11	\$7,790	77.15
3 RTI Biologics Inc	RTIX	\$3.85	\$209	66.44
4 NuVasive	NUVA	\$39.93	\$1,500	38.46
5 Synthes	SYST.VX	\$115.99	\$13,765	36.07

### Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 ArthroCare	ARTC	\$20.00	\$533	0.47
2 Symmetry Medical	SMA	\$9.86	\$353	0.88
3 Orthofix	OFIX	\$29.46	\$506	0.92
4 CryoLife	CRY	\$7.41	\$210	0.92
5 Exactech	EXAC	\$15.36	\$196	0.98

### Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 NuVasive	NUVA	\$39.93	\$1,500	4.10
2 RTI Biologics Inc	RTIX	\$3.85	\$209	1.91
3 CONMED	CNMD	\$18.51	\$538	1.62
4 Johnson & Johnson	JNJ	\$59.73	\$164,600	1.62
<b>5 Average</b>			<b>\$10,091</b>	<b>1.50</b>

### Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 CONMED	CNMD	\$18.51	\$538	0.80
2 Osteotech	OSTE	\$4.26	\$77	0.81
3 Symmetry Medical	SMA	\$9.86	\$353	0.86
4 Orthofix	OFIX	\$29.46	\$506	0.94
5 Exactech	EXAC	\$15.36	\$196	1.17

### Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$6.42	\$158	220.49
2 Mako Surgical	MAKO	\$8.64	\$217	10.74
3 Synthes	SYST.VX	\$115.99	\$13,765	8.41
4 NuVasive	NUVA	\$39.93	\$1,500	4.93
5 Regen Biologics	RGBO.OB	\$0.75	\$7	4.89

Advertise with Orthopedics This Week




[Click Here for more details](#)

or email [tom@ryortho.com](mailto:tom@ryortho.com)  
Tom Bishow: 410.356.2455 (office)  
or 410.608.1697 (cell)

## Midwest TKR—Where's the Real Bargain?

By Scott Ellison, PearlDiver Large Joints Analyst

When measured by average facility charges alone, total knee replacement (TKR) procedures in the Midwest cost about 23% less than in other parts of the country. But are all the Midwest facilities part of this “bargain-basement” for knee replacements?

Smart shoppers rummage through bargain bins and sale racks to find the best deals, and they know that not every sale item is actually a real bargain. It might take some searching and a good deal of research to find genuine savings without compromising on quality. In the world of orthopedics, does that same principle hold true for TKR procedures as well?

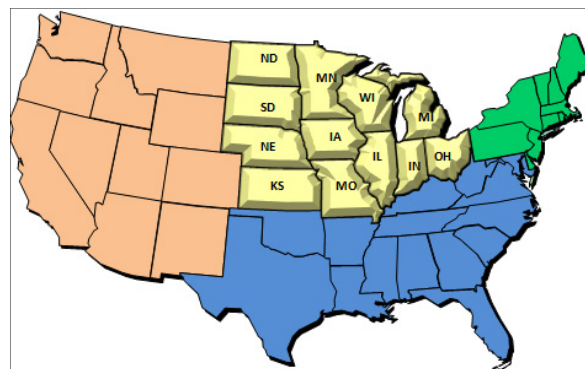
Total facility charges for a TKR have continued to rise over the last four years throughout all four regions of the U.S. (Northeast, South, West, and Midwest), and especially in the midst of an economic recession, more patients will try to stretch their dollars to get the most out of their money. But instead of booking the next



<http://commons.wikimedia.org>

flight to the first Midwest hospital near the airport, patients should take a close look at how procedure volumes, length of stay, and geographic location within the region affect the total charges.

Table 1 displays the number of TKR procedures by region over the past



Source: RRY Publications LLC

Table 1: U.S. Total Knee Replacements by Region

	2006	2007	2008E
Midwest	165,863	174,187	167,125
Northeast	84,274	93,057	94,610
West	89,248	96,331	101,925
South	202,616	218,154	229,123
Total Knee Replacements	542,000	581,730	592,783

Source: PearlDiver MedPAR Database, 2004-2008

**ORTHOFIX RESPONDS**

Responding to you for better patient outcomes.

See our new product offerings at NASS Booth 523

[www.orthofix.com](http://www.orthofix.com)

Fusion | Biologics | Bone Growth Stimulation  
MIS | Bracing

**ORTHOFIX**  
Spine

advertisement

three years. PearlDiver estimates that physicians performed over 580,000 total knee replacements in 2007 and 592,000 in 2008. Of those TKR procedures, 39% took place in the South, 16% in the Northeast, 17% in the West and 38% in the Midwest.

## Average Charges

From 2004 through 2008 the increase in charges for TKR procedures has shown no sign of slowing down. In the Midwest, charges have increased over \$6,000 since 2004 for both private payers and Medicare patients. That represents an increase of 18.7% for private payers and 21.2% for Medicare patients. For payers outside the Midwest, the average charges have increased in excess of \$9,600 for private payers and over \$8,000 for Medicare patients, increases of 23.7% and 21.6%, respectively. Chart 1 illustrates this increase in facility charges from 2004 to 2007 for the Midwest and regions outside of the Midwest.

According to the PearlDiver Private Payer Database, at the end of 2007, total facility charges for TKR for the average private payer were \$38,970 in the Midwest versus \$50,615 outside of the Midwest. This \$11,645 difference,

which amounts to a 23% discount, certainly makes the Midwest seem like an attractive region for bargain hunters.

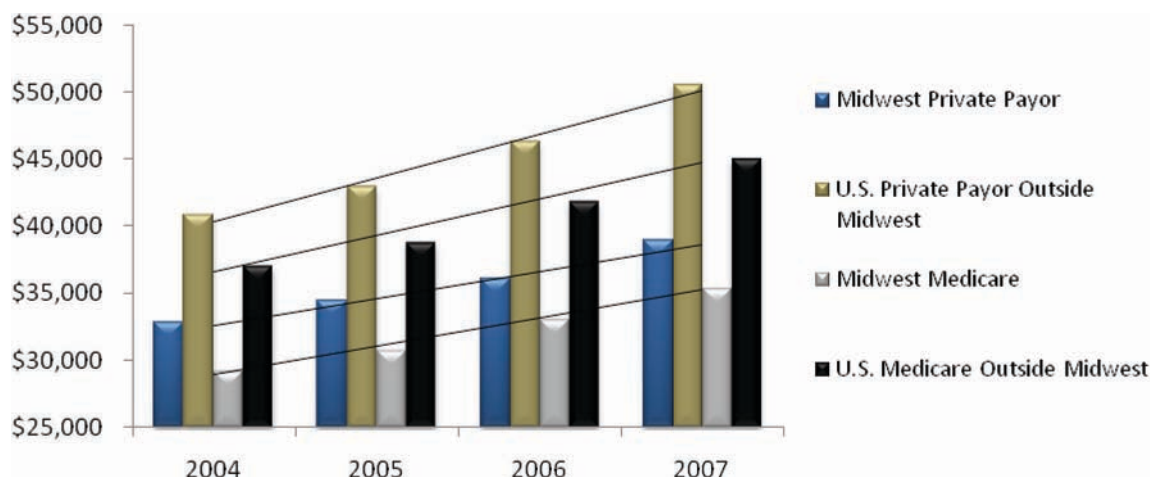
However, patients still need to do their research. The PearlDiver MedPAR Database reveals that within the Midwest, there were enormous variations in the charges made by facilities doing 100 or more TKR procedures in 2008. On the low end, facilities such as Northern Michigan Hospital in Petoskey, Michigan, charged an average of \$19,137 for a total knee replacement. At the other end of the spectrum, facilities such as the Methodist Medical Center in Peoria, Illinois, averaged \$62,530 for the same procedure. That is a difference of \$43,393, more than the total cost of the procedure in many places.

Despite these differences across the Midwest region, there is one

advertisement

discernable pattern: economies of scale. As the number of procedures performed at a facility increases, the number of facilities charging over \$50,000 quickly drops, coming to zero among facilities doing over 400 procedures annually. Chart 2 illustrates this pattern.

Chart 1: Average Facility Charge for Total Knee Replacement



Source: PearlDiver Private Payer Database, 2004-2007 and PearlDiver MedPAR Database, 2004-2008

# \$950 for the most popular U.S. Orthopedic Market Reports

## From the Data Guys at PearlDiver



The end of the quarter is here and our boss, Robin Young, is pushing us to get these reports out the door. We just loaded Medicare data into the system. Then we cross-referenced Medicare with our Private Payer datasets. So now he wants us to start selling. With more than 200 million patient records we have the largest, most granular market studies available for U.S. markets. Robin's telling us that we have to move the inventory. Every report listed below is just \$950. If you call us individually, we can give you volume discounts. The sooner we can get back to crunching numbers, the happier we'll be. These are great reports and we want to move them out.

(2004-08 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

To order contact Heather Truex: [heather@pearldiverinc.com](mailto:heather@pearldiverinc.com) or 260-469-4161

Spine Procedure	Code
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal fusion	81.04
Posterior dorsal fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Posterior lumbar refusion	81.38
Discectomy	80.51
Spinal Decompression	3.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Implant Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

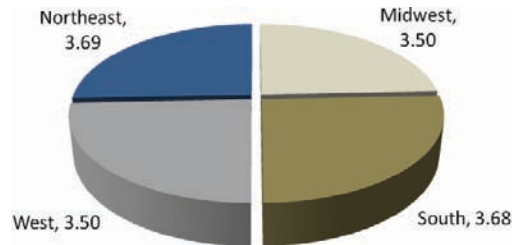
While the high-end average charges drop as the number of procedures increases, something else also occurs. The low-end facilities are raising their prices. The intuitive expectation would be that an increase in procedure volume would result in a lowering of average charges as a result of these economies of scale. However, the opposite trend also appears to be true. Chart 2 illustrates that as the number of procedures increases, the average facility charges approach a middle point.

### Length-of-Stay

The Midwest is tied for the shortest average length-of-stay (LOS) although differences by region are minimal as shown in Chart 3.

Within each region the LOS can vary by facility. How much does LOS

**Chart 3: Average LOS by Region**



Source: PearlDiver MedPAR Statistics, 2008

affect charges? Surprisingly little. Of the facilities doing over 100 annual TKR procedures, the top ten with the highest average charges were split with five facilities averaging a LOS of three days and the remaining five facilities with four days. Of the ten facilities with the lowest average charges, four averaged an LOS of four days, the next four facilities averages an LOS of three days and two facilities averaged an LOS of two days. Clearly, the LOS is

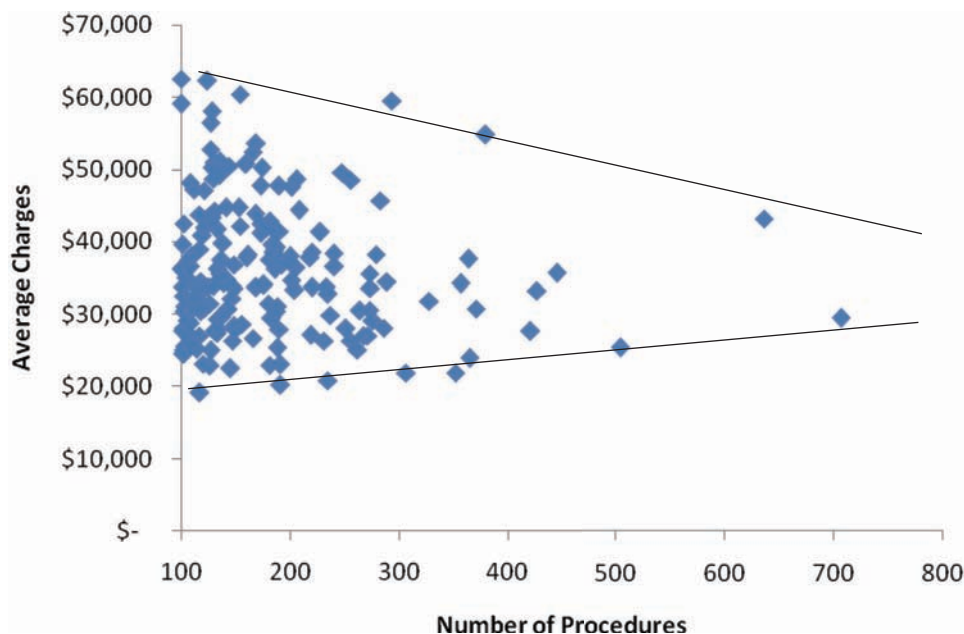
not driving the average charges for TKR when three of the facilities with the lowest charges are averaging a four day LOS.

### Geography

Within the Midwest, the percentage of total procedures is not evenly spread geographically among the 12 states. According to PearlDiver MedPAR statistics, 57% of the procedures performed in 2008 were done within three states, Illinois, Ohio and Indiana. North and South Dakota together accounted for only 4% of all total knee replacements within the Midwest.

Nine of the ten facilities at the top of the list for highest charges are in Illinois and Ohio, two of the three states comprising 57% of Midwestern TKR procedures as shown in Table 2.

**Chart 2: Total Knee Replacement Average Facility Charges for Midwestern Facilities by Volume**



Source: PearlDiver MedPAR Statistics, 2008

Of the facilities with the lowest charges in the Midwest, only one is from the top three states by procedure volume, shown in Table 3.

### Impact on Reimbursement

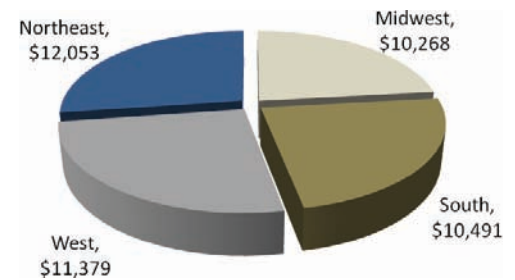
Another big difference within the Midwest “bargain basement” concerns the amount paid for total knee replacements. This varies greatly depending on who is paying—Medicare, private insurance, etc. The PearlDiver MedPAR statistics provide

insight into the true variance in reimbursement.

The Midwest remains the “bargain basement” of the country when reimbursement is compared to facility charges. As demonstrated in Chart 4, on average, Midwestern facilities receive the lowest average reimbursement while facilities in the Northeast receive the most.

Do reimbursements vary in the same degree that the charges do? Of facilities

**Chart 4: Average Reimbursement by Region**



Source: PearlDiver MedPAR Statistics, 2008

within the Midwest that perform at least 100 TKR procedures annually, the

**Table 2: Highest Average Charges in Midwest by Provider**

	Provider	Location	Avg Charge
1	Methodist Medical Center of Illinois	Peoria, IL	\$62,530
2	Good Samaritan Hospital and Health Center	Dayton, OH	\$62,272
3	Adventist Hinsdale Hospital	Hinsdale, IL	\$60,436
4	Central Dupage Hospital Association	Winfield, IL	\$59,516
5	Provena Hospitals	Joliet, IL	\$59,056
6	Elmhurst Memorial Hospital	Elmhurst, IL	\$58,011
7	Shawnee Mission Medical Center	Shawnee Mission, KS	\$56,407
8	Rush University Medical Center	Chicago, IL	\$54,851
9	Bethesda Hospital	Cincinnati, OH	\$53,597
10	Western Reserve Care System	Youngstown, OH	\$52,804

Source: PearlDiver MedPAR Statistics, 2008

**Table 3: Lowest Average Charges in Midwest by Provider**

	Provider	Location	Avg Charge
1	Northern Michigan Hospitals	Petoskey, MI	\$19,137
2	Munson Medical Center	Traverse City, MI	\$20,213
3	Lakeview Memorial Hospitals	Minneapolis, MN	\$20,870
4	Spectrum Health Hospitals	Grand Rapids, MI	\$21,911
5	Kansas Surgery & Recovery Center	Wichita, KS	\$21,960
6	St. Luke's Episcopal Presbyterian Hospital	Chesterfield, MO	\$22,530
7	Trinity Hospitals	Minot, ND	\$22,885
8	MidMichigan Medical Center	Midland, MI	\$23,021
9	Mercy Medical Center of Oshkosh	Menasha, WI	\$23,065
10	Protestant Memorial Medical Center	Belleville, IL	\$23,181

Source: PearlDiver MedPAR Statistics, 2008

highest reimbursement for any facility was \$16,686 while the lowest average was \$6,564. That is a difference of \$10,122 or 154% which is nowhere near the variance of charges which peaked at 227% of the lowest average charge in the Midwest. Although reimbursement varies depending on the facility, the variance is fortunately not to the same high degree as the variances in charges.

For the area of the country known for its low cost total knee replacements, charges still vary greatly from one facility to the next. In terms of both facility charges and reimbursement, we found enormous differences between the high and low ends of the spectrum. Length of stay may have surprisingly little to do with total facility charges, but a facility's geographic location and annual

procedure volume can translate to huge differences in costs. So even if the Midwest gets dubbed the "bargain basement" for TKR, not all facilities within the Midwest are created equal. If you're hunting for a real bargain, you still need to do your research.



## On Message: Media Training for Orthopedists

By Elizabeth Hofheinz, M.P.H., M.Ed



If you're as well known for bloopers as you are for osteotomies, you might need to spend a few hours working on your "message."

Andrew Gilman, President and CEO of CommCore Consulting Group, knows how to work with the media. "If you are in a position of responsibility in a state, local, or national orthopedic society then interacting with the media could be part of your job description. Alternatively, an orthopedist could use media training as part of his or her practice development strategy. Getting quoted in an article or appearing on television can go a long way toward getting the message out that you are a qualified expert in your field."

Gilman, who has done proactive media training, as well as crisis training going back to the Johnson & Johnson Tylenol crisis, states,

"Many physicians don't understand that how they should behave with the media is not how they should conduct themselves in a deposition. Media training teaches people that keeping quiet is not the goal. Instead, one ought to take the opportunity to deliver appropriate information to different audiences about specific subjects. Learning how to interact with the media, either on an offensive or defensive basis, helps you learn skills that allow you to take scientific and/or medical information and translate it into layman's language that is appropriate for children, caregivers and individuals in the healthcare field as well as legislators."

### Preparing Your Message

And the mother of a young athlete will likely have different concerns than a lawmaker. To formulate an appropriate message, says Gilman, it is important

to know your audience. "The first component of media training is an explanation of how the media thinks and operates. While you are talking directly to the person in front of you, in a sense you are talking past them as well, to the wider audience. Make sure you understand what they want to know."

As for what the media representative will ask, you will likely be greeted by a litany of "Ws." Andrew Gilman explains, "The interviewer will usually ask you the medical version of the five 'Ws'—who, what, why, where, and when. Specifically, they will want to know the causes of a problem, the symptoms, the treatment options, the treatments you recommend and why, the results that the patient can expect, things to watch out for, alternatives to surgery, potential side effects, rehab and insurance related questions."

So that you're not entering this blizzard of questions blindly, however, Gilman suggests that you take the offensive position as well. "You should ask reporters nearly as many questions as they ask you, along the lines of, 'Who are you? What publication do you represent? How did you get my name? What kind of story are you doing? What do you know so far?,' etc. That way you have a better idea of the reporter's expectations, the goal of the story, and the needs of the audience."

Just like you have the steps of a knee replacement nailed down, you should also be certain of your "message." Andrew Gilman: "When I was getting ready for a hip replacement I had

# The choice is clear



## AmnioClear™

Use in place of synthetic based options such as films, bovine collagens, or wraps

We may be new to the market, but our material established the category. AmnioClear is the only natural, amnion-based in vivo wound covering, which delivers the natural function of amnion to the surgical site. AmnioClear can be used in the spine to cover laminectomies and anterior lumbar procedures, conforming more naturally and completely to each location. **Natural material, natural choice... and the body knows the difference.**

[www.AFcellMedical.com](http://www.AFcellMedical.com)

7235 Vicksburg Pike, Fort Wayne, IN 46804

Lit No.: 04150009 Published 05/09





read about the surgery, including the MIS option versus the old fashioned long incision. My doctor was totally prepared with a pithy example that drove his point home. He said, 'I could give you the statistics on MIS or I could just say, 'Look, if you want to get into a house you can go in through a window or through the front door.'

His analogy beautifully captured what would otherwise have been a long answer."

"The best communicators can explain difficult subjects in very memorable ways...but that is not natural. It comes with training and preparedness. If I'm getting ready for an interview with a

health magazine I will develop three or four tips on what patients should do if they are having orthopedic problems. If you have such information ready beforehand, you are ahead of the game."

Whether it was the white light shone upon you by your kindergarten teacher or by that plaintiff's attorney last month, many orthopedists, literally and figuratively, lose the power of speech. "Because of school teachers and attorneys peppering them with questions, most doctors are a bit scared during interviews," says Gilman. "The majority of doctors come out of an interview, and when I ask if they got all their information across, they say, 'Well, the reporter wasn't interested in that' or 'He didn't ask the right questions.'"

"Your job is to get your information out there, so you have to be assertive with your message. To be able to do that most effectively, you should begin to think through what you want to communicate beforehand. Like grand rounds you need a plan. Seven out of ten reporters lead off with a question along the lines of, 'Tell me about XYZ procedure.' If, for example, the surgery concerns osteoporosis, you have an opportunity to frame the discussion and educate the audience about the latest research and treatment advances. Don't be afraid to be as 'in charge' as the reporter."

### Getting on Defense and Avoiding Pitfalls

While you don't have to be armed to the teeth, the fact is, says Gilman, interviews often require some defensive action. "You should

anticipate the hard questions so that you are not caught off guard. If the topic is hip replacement surgery, you need to be prepared for questions related to complications, such as infection. There are techniques for handling those questions. One such strategy is bridging: answering the direct question and the making a transition to a related positive point. An example: 'Yes, infection is a potential risk in any operation. However, we take all of the appropriate precautions.' Then bridge to your experience and results."

"Or, perhaps the reporter inquires about your knowledge of the recent Department of Justice investigation. While you don't have to go into depth, it is best to have a general knowledge of the issue and have a basic answer at the ready. It is completely appropriate to say, 'That actually doesn't apply to me, but I can suggest that you call the American Academy of Orthopaedic Surgeons.' This sounds much better than saying, 'No comment.'"

In order to sail through interviews, you need to walk through them several times first. "You really can't learn how to interact effectively with the media unless you practice. The most dynamic and efficient way to do this is with videotaping. While most people, including doctors, cringe a bit when seeing themselves on tape, I tell them that you can't learn to swim if you're sitting at the pool reading a book. If videotaping is more painful than watching your golf swing on tape, you might try finding someone to role play questions with you. With videotaping, however, most

people find that they are not as bad as they think, with the second or third practice usually sealing it. Armed with these new skills, you will have more mental energy to think through things and strategize."

And be careful not to get caught in quicksand, says Gilman. "One of the pitfalls that you can get into is going beyond your expertise. This may involve, for example, talking about things that are more appropriately handled by a device manufacturer or pharmaceutical company. If the conversation turns this way you need only say, 'That is beyond my expertise.'"

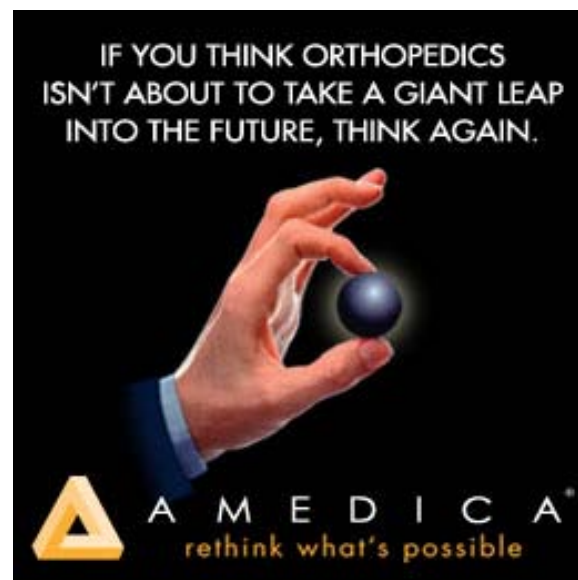
"Another thing that creates a challenge for a doctor during an interview is the prescription of medication. In the current regulatory environment there is a lot of concern about off label uses, with many pharma and device companies promoting such use. In this type of situation, you can just say, 'As you may know that is an off label use. Depending on my clinical judgment I may or may not decide to use it.'"

When the red flags do start flying, just stop and think. "You do not have to answer every question a reporter asks you. Don't just leave them hanging, however. Say, for example, 'I would prefer not to speculate on that subject, but here is what I can tell you.' Also, if you are asked for your personal opinion, you may say, 'Well, I can give you my expert opinion.' If a reporter asks three or four questions in a row, you may select one to answer. And whatever you do, don't comment on what one of your colleagues has done."

You should also avoid the classic mistake, says Gilman, of repeating the negative in a question. "For example, years ago President George Bush senior was asked, 'There are rumors that your administration is adrift and is experiencing malaise. Is this true?' He replied in a negative vein, saying, 'I disagree. I don't see any malaise.' Then he gave a laundry list of things that he said the administration had done right. The headline the next day was, 'Bush Sees No Malaise, Denies Drift.'"

"Instead of repeating the negative," recommends Gilman, "it would have been better to think through the question, then pause and say, 'I disagree. That's not the way we look at it and that's not what we're hearing from voters.' Most people answering questions genuinely want to be helpful so they start answering right away. While a reporter is not necessarily trying to trap the interviewee, they are trained to be skeptical."

This is another case where bridging can help, advises Gilman. "Let's say a reporter asks, 'Doesn't this drug have the same efficiency



advertisement

as other drugs in this category, according to the FDA?' You can respond, 'Yes, it is basically effective, however I believe that when there is a once a day option we will see better patient compliance.'"

The essence of working with the media involves doing what orthopedists do well anyway...careful, well thought out preparation. Andrew Gilman: "Give some consideration to why you are doing the interview and why you are answering specific questions. Are you trying to get a message across to fellow doctors, patients, or hospital

administrators? If are you doing the interview to grow your practice, don't forget to include information like your website. Just as in the OR, the more you plan, the less likely things are to go awry."



**SAFETY**  
FROM THE BEGINNING

Our commitment is to exceed industry standards at every step of the process from procurement to the distribution of each allograft.

**LifeGraft®**

Introducing LifeGraft® Allograft Tissue

- Designed to promote fusion
- Built for structural support
- Texturized to help prevent migration
- Unique instrumentation for efficient sizing and delivery of graft

**LifeLink® Tissue Bank**

[www.lifelinktb.org](http://www.lifelinktb.org)

advertisement

## Cabo Meeting Moves to Scottsdale

Spine Technology Education Group  
6th Annual Symposium

### Innovative Techniques in Spine Surgery

October 15 – 17, 2009

The Phoenician Resort ♦ Scottsdale, Arizona

Join us at Arizona's premier destination resort for frank discussion around effective management of spinal disorders. In addition to our prestigious faculty of clinicians, researchers, educators, and developers of spinal technology, Robin Young will lead a seminar titled "The Changing Economics of Surgery: Reimbursement, Regulation and Disclosure."



Register today or find more information at:  
(858) 279-9955, [pmc@mtgplanner.com](mailto:pmc@mtgplanner.com), or  
[www.medostar.org/steg/event.php](http://www.medostar.org/steg/event.php)



advertisement

## Fusion ICD Codes Changing?

By Walter Eisner

The “devil in the details” of CMS (Centers for Medicare and Medicaid) reimbursement lies in the nomenclature of the ICD-9-CM procedure codes. Those codes are reported by hospitals to classify inpatient procedures. Then they’re combined with ICD-9-CM diagnosis codes to determine the DRG placement and subsequent payment to the hospital. When the codes get messed with, your reimbursements can change.



CMS is in the midst of considering revisions to, among others, codes for spine fusion procedures whose technologies have sprinted ahead of their current codes.

The last time CMS tackled significant code changes for spine procedures was four years ago when the agency developed codes for motion preservation procedures.

Kelli Hallas, Vice President of Reimbursement Services at Emerson Consultants, tells us that the agency

has received several requests and recommendations to revise the current fusion codes to reflect the changing environment.

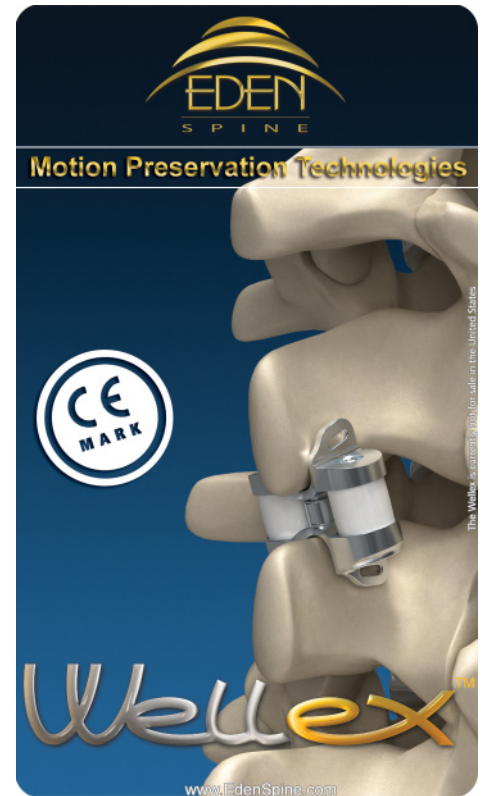
### Categorized Forever?

When CMS developed the motion preservation codes, there was a lot of public and industry participation. According to Hallas, this time the changes are taking place without the participation of many smaller and mid-sized spine companies. At a September 16 CMS Coordination and Maintenance Meeting, Hallas says very few device manufacturers showed up and if they don’t get involved, their products may end up being categorized in codes they don’t like.

“It is imperative that companies review these proposed changes and determine the strategic impact (if any) to their business,” says Hallas.

If they get involved now, Hallas hopes that some of the smaller companies and newer technologies will be able

to accurately provide information on their technology early on.



advertisement



## Fusion Alphabet Soup

“Pay attention to the terms included in the ‘Add inclusion term’ proposed revisions,” said Hallas.

Those terms include DLIF, XLIF, AxiaLIF and others.

Go to PearlDiver spine analyst Matt Menze’s Web page (<http://www.pearldiverinc.com/pdi/spine.jsp>) to see a U.S. Spine Fusion Summary 2006-2012 of volume of fusion procedures.

In a summary report of the September 16 meeting, CMS specifically cited support for the “EXtreme Lateral Interbody Fusion (XLIF) and Direct Lateral Interbody Fusion (DLIF) inclusion terms being proposed at code 81.06, Lumbar and lumbosacral

fusion, anterior technique, versus code 81.08, Lumbar and lumbosacral fusion, posterior technique.”

The summary report also noted the comments from those who expressed their support of the proposed spinal fusion/refusion code title revision that would identify which column is being fused.

Andrew Cappucino, M.D., board certified in spinal surgery and orthopedic surgery, specifically stated that it is important to distinguish that the XLIF procedure uses a true anterior approach.

CMS staffer Mady Hue explained at the meeting that these same revisions would also apply to the spinal refusion codes. She also noted that this category of codes presented challenges, as both the approach and the technique concepts were historically included in this set of codes and no longer accurately apply in today’s environment.

Not everyone is in favor of the suggested changes. There are some who prefer a complete freeze on changing codes until a new and better way is devised to capture technology changes in new techniques.

Hallas says the proliferation of procedures and devices has caused confusion with providers who are not always sure which code most closely fits the procedure.

“Companies need to be sure they understand the payment implications from a change in the codes,” added Hallas.

CMS is accepting comments to the proposal below until November 20, 2009. Comments should be sent to Mady Hue at CMS ([Marilu.hue@cms.hhs.gov](mailto:Marilu.hue@cms.hhs.gov)).

On the following page were the changes presented at the September 16 ICD meeting:



**P&M CORPORATE FINANCE, LLC**  
INVESTMENT BANKING FOR THE MIDDLE MARKET

**UNMATCHED ACCESS.  
UNCOMPROMISING RESULTS.**

Strategic Sale Advisory  
Capital Raising  
IP/Product Line Divestitures  
Targeted Acquisition Search  
Strategic Consulting

[www.pmcf.com](http://www.pmcf.com)

**MEDICAL DEVICE**  
Market Overview Now Available >>

advertisement

**Spine Fusion ICD-9-CM Procedure Codes Presented for Change in the Addenda  
of the September ICD-9-CM Coordination and Maintenance Committee Meeting  
81.0 Spinal Fusion**

Add note		Note: An interbody fusion is a fusion of the anterior column of the spine. The anterior column can be fused using an anterior, lateral, posterior, combined (anterolateral) (posterolateral) or a percutaneous technique. A posterior column fusion can be performed using a posterior, percutaneous, posterolateral or lateral transverse technique.
Revise code title	81.02	Other cervical fusion of the anterior column, anterior technique
Revise code title	81.03	Other cervical fusion of the posterior column, posterior technique
Delete inclusion term		Arthrodesis of C2 level or below: <del>Posterior (interbody) technique</del>
Revise code title	81.04	Dorsal and dorsolumbar fusion of the anterior column, anterior technique
Add inclusion term		Posterolateral technique
Revise code title	81.05	Dorsal and dorsolumbar fusion of the posterior column, posterior technique
Delete inclusion term		Arthrodesis of thoracic or thoracolumbar region: <del>Posterior (interbody) technique</del>
Delete inclusion term		<del>Posterolateral technique</del>
Revise code title	81.06	Lumbar and lumbosacral fusion of the anterior column, anterior technique
Add inclusion term		Arthrodesis of lumbar or lumbosacral region: Direct lateral interbody fusion [DLIF]
Add inclusion term		EXtreme lateral interbody fusion [XLIF]
Add inclusion term		Retroperitoneal
Add inclusion term		Transperitoneal
Revise code title	81.07	Lumbar and lumbosacral fusion of the posterior column, posterior <del>or lateral-transverse process</del> technique
Add inclusion term		Transverse process technique
Revise code title	81.08	Lumbar and lumbosacral fusion anterior column, posterior technique
Delete inclusion term		Arthrodesis of lumbar or lumbosacral region: <del>Posterior (interbody) technique</del>
Add inclusion term		Axial lumbar interbody fusion [AxiaLIF]



## company news

**Custom Spine Makes Herrington Sales Chief**

**F**rank Herrington joined Custom Spine this past March as Vice President of Sales for the Southeast Region. On September 8, the company announced that he was being promoted to Senior Vice President of Sales and Marketing.



Frank Herrington

Custom Spine has undergone a number of changes since Lew Bennett became President this past January. Bennett has been in the industry for 48 years and has probably learned to judge talent.

Herrington had 27 years of orthopedic and medical device marketplace experience before joining Bennett in March.

Bennett said, "As a company, we are continuing to move forward with our growth strategy with emphasis being placed on our sales and distribution network. Frank has shown strong leadership skills that will further lead to the company's growth and success."

Custom Spine was founded in 2003 by engineers and industry professionals in partnership with orthopedic and neurological spine surgeons. Mahmoud Abdelgany is the company's CEO and, according to the company, the creator of the company's implants and instruments.

Custom Spine's flagship product the ISSYS Polyaxial Pedicle Screw System has given birth to the ISSYS LP Low Profile Spinal Fixation System, the ISSYS LP Monoaxial Screw and Staple System, and the ISSYS LP PAC Polyaxial Connector.

The company is privately held and is headquartered in Parsippany, New Jersey.

—WE (September 30, 2009) 

## legal &amp; regulatory

**Kyphon Whistleblowers Strike Again**

**T**he whistleblower lawsuit that accompanied Kyphon to Medtronic has claimed another provider.

For the second time in six months we've seen a group of hospitals reach multi-million dollar settlements with the Justice department for alleged false claims involving kyphoplasty procedures. This sits on top of the original Kyphon

settlement with the Justice Department at the time Medtronic was paying \$4 billion to acquire Kyphon.

This time, six hospitals in Indiana and Alabama settled for \$8 million. This could get expensive.

Between 2002 and 2008 the hospitals, allegedly, overcharged Medicare every time they performed a kyphoplasty procedure. They allegedly did this by keeping patients in their hospitals overnight instead of performing the procedure on an out-patient basis.

Said Daniel Levinson, Inspector General for the U.S. Department of Health and Human Services,

"Hospitals that overcharge Medicare drain critical funds from the Medicare program and increase health care costs. This settlement demonstrates the Federal government's resolve to address this kind of fraudulent conduct."

**Minnesota Settlements**

Three Minnesota hospitals reached a \$2.28 million settlement this past



## legal & regulatory

June for alleged kyphoplasty-related Medicare fraud claims.

In May 2008, Medtronic settled with the Justice Department for \$75 million to settle allegations that the company defrauded Medicare by counseling hospitals to perform kyphoplasty procedures as an in-patient procedure,

The Indiana hospitals include St. Francis Hospital in Beech Grove, Deaconess Hospital in Evansville and St. John's Hospital System in Anderson. The hospitals have agreed to pay the United States \$3,158,629, \$2,110,034 and \$826,256, respectively.

The Alabama hospitals include St. Vincent's East Hospital and St. Vincent's Birmingham Hospital, both located in Birmingham, and Providence Hospital, located in Mobile. These facilities have agreed to pay the United States \$1,459,395, \$422,748 and \$381,713, respectively.

### Whistleblowers Return

This lawsuit was filed in 2008 in federal district court in Buffalo, New York, by the same two former Kyphon employees who initiated the original suit against Kyphon. Craig Patrick is a former reimbursement manager for Kyphon and Charles Bates was a former regional sales manager for Kyphon in Birmingham, Alabama. The two will receive approximately \$1.4 million as their share of the settlement proceeds of this qui tam suit.

—WE (September 30, 2009) 

### FDA Seeks Internet Promotion Input

The FDA wants to hear what you think about promoting your medical device on the Internet and social media sites such as Facebook, YouTube, Wikipedia, Twitter and others.

The agency is evaluating how statutory provisions, regulations, and policies concerning advertising and promotional labeling should be applied to product-related information on the Internet and newer technologies.

A public hearing on the topic will be held on November 12 and 13 at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, SW., Washington, D.C. 20594.

Don't worry, if you can't make the meeting, you can contact them on the Internet at <http://www.regulations.gov>, and reference [Docket No. FDA-2009-N-0441]. Written and electronic comments will be accepted until February 28, 2010.

The FDA wants to hear about the following questions:

1. For what online communications are manufacturers, packers, or distributors accountable?
2. How can manufacturers, packers, or distributors fulfill regulatory requirements?
3. What parameters should apply to the posting of corrective information on web sites controlled by third parties?
4. When is the use of links appropriate?



**COMMITTED TO DEVELOPING A  
NONSURGICAL  
CHOICE FOR  
DUPUYTREN'S DISEASE**

AUXILIUM is a specialty biopharmaceutical company committed to developing innovations for unmet medical needs like Dupuytren's disease.

Enroll now at [ja.ddfacts.com](http://ja.ddfacts.com) to get free patient education tools and information about Dupuytren's disease.

**AUXILIUM** © 2009 Auxilium Pharmaceuticals, Inc. XIA-122.a

advertisement

## legal & regulatory

### 5. How do social media impact adverse-event reporting?

There are currently no regulations that specifically address Internet promotion separately from the other types of promotion, nor are there any regulations that prohibit the use of certain types of media to promote drugs and medical devices.

“Although no rule has specifically addressed Internet promotion, it is fairly clear that some promotional efforts are substantially similar in presentation and content to promotional materials in other media or publications. At the same time, FDA recognizes that the Internet possesses certain unique technological features and that some online tools that may be used for promotion offer novel presentation and content features,” stated the meeting announcement on September 21, 2009.

Some companies have received warning letters from the FDA relating to their web promotions and this meeting is an effort to find clear guidelines for promotions on the Internet.

—WE (October 1, 2009) 

## extremities

### Alpha Orthotics: New Foot Brace in the U.S.

No flatfoots on the beat here...just a company trying to round up the best option for splayfoot, aka “fallen



Town Hall Meeting/Temple.edu

arch.” According to Alpha Orthotics Corporation, developer of the Medial Mid-foot Brace, an estimated 20%-30% of Americans have this condition where the arch never develops, or collapses in one or both feet. Alpha, a wholly owned subsidiary of German Hallux Corporation, has just announced the launch of the Medial Mid-foot Brace in the U.S. (It debuted in Europe earlier this year.) As indicated by the company, this one size fits all brace provides longitudinal arch support, relieving mid-foot pain caused by general foot stress and strain including splayfoot and fallen arch. The same device can be worn on either the right or left foot and the brace is thin enough to slip into non-restrictive dress or casual shoes.

“Fallen arch is a very common problem which can cause tremendous pain,” stated Gaby Federal, President of Alpha Orthotics Corporation, in the news release. “Our Medial Mid-

foot Brace is a simple and effective pain relief device people can use while engaging in sports activity such as running, tennis and golf, and for people who need to be on their feet and active or work.”

The Medial Mid-foot Brace system consists of a splint, a foam cushion, a metatarsal strap and a metatarsal pad. The thin profile cushioned splint braces the inside border of the foot. The dual strapping system provides inward and upward support to the mid-foot, while the metatarsal pad provides lift to the transverse arch.

Flat feet can develop as an adult due to injury, illness, unusual or prolonged stress to the foot, faulty biomechanics, or as part of the normal aging process. This condition can also occur in pregnant women as a result of temporary changes, due to increased elastin (elasticity) during pregnancy. However, if developed in


## extremities



Medial Mid-foot Brace/Alpha Orthotics Corporation

adulthood, flat feet generally remain flat permanently.

Regarding European users of the brace, Gaby Federal told *OTW*, “The healthcare system in Europe is all about prevention, and orthotics like the Medial Mid-foot brace are used regularly to keep mild and moderate painful foot maladies from turning into serious cases. People who are on their feet at work such as doctors, soldiers and nurses use the brace to alleviate general foot stress and strain including splayfoot and fallen arch. Active and athletic Europeans often have mid-foot inflammation and have also had great success using the brace to continue being involved in the sports they love such as tennis, golfing, walking and jogging without the foot pain.”

—EH (October 2, 2009) 

### Medicrea Launches New Product and Study


**M**edicrea is expanding its footprint in America.

The French-based orthopedic spinal implant company announced on September 24 that it has launched its PASS LP De-Rotation connector in the U.S., and is preparing a U.S. prospective multicenter clinical study analyzing the 3D correction of adolescent idiopathic scoliosis by posterior instrumentation.

The aim of the study is to evaluate the clinical, functional and radiographic outcomes following the reduction of adolescent idiopathic scoliosis using Medicrea’s PASS system. The study is scheduled to begin in early 2010 and the complete follow-up period will last for three years. The first clinical results are expected to be published at the end of 2011.

The company says the PASS system has a unique technique that allows for the treatment of long and complex deformities or curvature (i.e., scoliosis, kyphosis, and/or lordosis.) The rods are pre-bent to the desired curve in the sagittal plane. What makes the PASS system unique compared to other fixation systems on the market, according to the company, is that progressive reduction of the deformity is achieved

by alternately tightening all the nuts on both rods at the same time thereby significantly reducing the stress applied on the screws and hooks. Since entering the U.S. market in 2007, Medicrea has increased its U.S. revenues from \$1.9 to \$3.6 million in 2008 and approximately \$8.5 million in estimated sales in 2009. The company operates from its headquarters based in Lyon, France, with a manufacturing facility located in La Rochelle, France, and three distribution subsidiaries in the U.S., UK and France.

—WE (September 29, 2009) 

### Antibodies May Worsen Spinal Cord Damage

**R**esearchers from The Ohio State University Medical Center may have solved a CNS mystery. Working with mice, this team of neuroscientists has learned that the antibodies released after a spinal cord injury may actually worsen and extend the spinal cord damage. The study, published online by the *Journal of Clinical Investigation*, found that the antibodies first attach to nerve cells and other elements of the nervous system, then other components of the immune system attack the cells and substances marked by the antibodies as if they were infectious agents or foreign material.

“Our findings suggest that inhibiting or depleting B lymphocytes, the cells that produce antibodies, may promote

## spine

healing and reduce the long-term effects of spinal cord injury,” said lead author Phillip G. Popovich, Ph.D., in the news release. Dr. Popovich is Director of Ohio State’s Center for Brain and Spinal Cord Repair and Professor of neuroscience and of molecular virology, immunology and medical genetics. “They may also help explain why the central nervous system does not repair itself efficiently and why other impairments often follow spinal cord injury,” he added.

The Ohio State team had previously demonstrated that B cells are activated as part of a general immune response following spinal cord injury, and that they accumulate around the spinal cord injury and begin producing antibodies. In this study, Dr. Popovich, first author Daniel P. Ankeny, and research associate Zhen Guan, used mice that were anesthetized and given a moderately severe spinal injury that mimics a contusion-type spinal injury in humans. One group of injured mice had a normal immune system, with antibody-producing B cells. The second group of mice was identical to the first except that they lacked B cells, and therefore produced no antibodies.

Nine weeks post-injury the researchers found that, on average, the area of spinal cord damage in mice without antibodies was 30% smaller than the damaged area in mice with antibodies. Also, B cells and antibodies had accumulated around the spinal cord in the normal mice but not in the other group; additionally, antibodies had attached to damaged areas of the spinal cord. They also found substantially

Global **SOLUTIONS**,  
Local **SERVICE**



A world away, or right next door -  
Symmetry is there to meet your needs. Our combined resources located throughout the U.S., Europe and Malaysia allow our dedicated design teams to develop innovative solutions for you, with exceptional results.



**SYMMETRY Medical**<sup>®</sup> Inc.

**Implants • Instruments • Cases**  
**Product Development • Total Solutions**<sup>®</sup>

[www.SymmetryMedical.com](http://www.SymmetryMedical.com)

advertisement



Photo Courtesy of Medicea

## spine

higher levels of antibodies in the bloodstream of the normal group after spinal cord injury than were present before injury.

The team then wondered whether these antibodies alone could damage the spinal cord. So, they purified the antibodies from the blood of injured mice and microinjected them into one side of the spinal cord of uninjured normal mice. Within 48 hours, the hind leg on the side of the injection site became paralyzed, and remained partially so after one week. The animals also showed loss of neurons and other damage to the spinal cord.

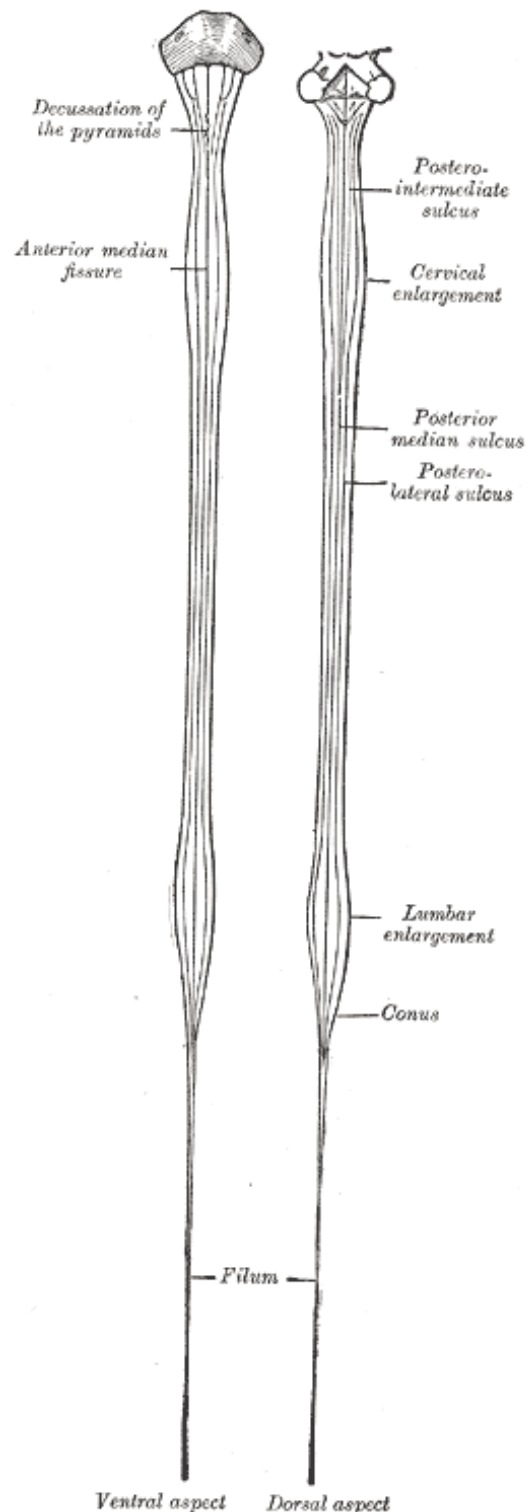
“This was one of the more striking, remarkable aspects of the study, the fact that the antibodies alone from an injured animal can activate an immune response that damages tissue in an uninjured animal,” said Ankeny, a research scientist in molecular virology, immunology and medical genetics, in the news release.

Dr. Popovich noted that, along with paralysis, individuals with spinal cord injury may also have systemic problems, such as chronic bladder problems. These are usually attributed to chronic catheterization and loss of bladder control, he says. “But that doesn’t explain changes that also occur in the kidneys. It may be that antibodies are targeting antigens within the kidney and causing kidney damage.” He also said, “Male sterility is a major problem in men with spinal injuries,” he says, “and there is no explanation for why this happens.”

Asked when human studies might begin, Dr. Popovich told *OTW*, “This is difficult to answer since we need to confirm the production of pathogenic autoantibodies in humans. For that to happen, we need to obtain human samples without the confounding effects of recent or concurrent immune responses (e.g., to infection). In our model, the animals are maintained in clean facilities and the antibody response can be directly linked to the injury. In humans, it will be more difficult to ‘find’ these antibodies among the plethora of antibodies that may exist in a given subject. We are constantly bombarded with potential pathogens and our immune systems are responding to these challenges by producing antibodies. We are currently trying to identify the proteins in the CNS (and throughout the body) that are targeted by these antibodies. Once we know that, we will know which antibodies to look for in the human population.”

As for what aspects of his work might be helpful for orthopedists to know, Dr. Popovich told *OTW*, “I think it is important to realize that there is a systemic response to spinal cord injury. In other words, most clinicians and basic scientists focus on changes occurring in the spinal cord. These data show that the effects of SCI transcend the injury site and that changes in cells and organ systems in the periphery can impact neurological function in ways that we have not considered.”

—EH (September 30, 2009) 



Spinal Cord/Wikimedia Commons



VISIT US AT NASS  
BOOTH #2313

Dynamic Solutions for the *Spine*



Introducing the Xenon<sup>™</sup> Pedicle Screw System Featuring the Isobar Evolution<sup>™</sup> Dynamic Rod:

- a comprehensive set of intuitive, surgeon-designed instruments
- a new, low-profile, dual-lead pedicle screw
- includes both dynamic and rigid rods

**SCIENT'X**

900 Airport Road, Suite 3B  
West Chester, PA, 19380  
Tel: +1 (610) 840 6200  
[www.scientxusa.com](http://www.scientxusa.com)

## spine

**Scient'x Introduces Dynamic Rod**

innovation and successful clinical outcomes, there is no company better

and has an improved lordotic radius for a better anatomic fit, easier insertion and optimal maintenance of sagittal balance.



Source: Scient'x

**S**cient'x introduced the Isobar Evolution Dynamic Rod on September 28. The France-based company says the rod is the cornerstone of its new Dynamic Solutions strategy and is an adjunct to posterior pedicle-based fusion.

Company President and CEO Oliver Burckhardt said the strategy positions Scient'x to be the world leader in providing Dynamic Solutions for both non-fusion and fusion procedures. [Non-fusion technologies are not available in the U.S.]. Dynamic Fusion, also known as semi-rigid fusion, immobilizes and stabilizes the spinal segment.

“Thousands of patients around the globe have already been treated with Isobar Dynamic Rods, and with our demonstrated commitment to

equipped to apply the concept of Dynamic Fusion to the treatment of lower lumbar spine pathologies,” said Burckhardt.

“The launch of the Isobar Evolution will allow us to build on these years of successful clinical outcomes by investigating the product’s potential impact on adjacent level degeneration in the future,” continued Burckhardt.

**Predecessor to Isobar Dynamic Rod**

The Isobar Dynamic Rod, the predecessor to the new Isobar Evolution, was the first semi-rigid rod introduced by Scient'x to the international market over 16 years ago. The company says the new rod has a 25% smaller dampener that allows for more versatile placement

**Castellvi and Perrin Testimonials**

“I have been using the semi-rigid dynamic interpedicular fixation system since June 1993, and my current personal experience is with more than 800 patients implanted. The justification for choosing such devices for my lumbar procedures was related to the quality of the biomechanical and clinical data that has accompanied this technology,” said Gilles Perrin, M.D. of Lyon, France.

A.E. Castellvi, M.D., of Tampa, Florida, commented, “I started using the Isobar Dynamic Rod in 2003 when it became available in the United States. The dynamic properties of this rod offered me the options I needed to provide high quality of care for treating my patients. The newly-launched Isobar Evolution offers me the same great technology with enhanced versatility due to the improved geometry.”

The new rod is intended to be used with the new Scient'x Xenonx Pedicle Screw System in the United States and will be compatible with several of the company’s pedicle screw systems available worldwide.

—WE (September 29, 2009) 

## trauma

**Prosthetic Leg Safety**

Stumbling towards innovation... Researchers are known for being tough, but not cruel. So when a team of investigators at the University of Rhode Island began tripping patients, everyone onboard knew it was all part of the plan.

Marjorie Brasier, a 71-year-old, was one of six clients of Nunnery Orthotic & Prosthetic Technologies to participate in the study, which aims to improve the safety of prosthetic legs by developing a reliable and responsive stumble detection system.

Marjorie Brasier, Michael Nunnery, and Dr. Helen Huang; /Courtesy University of Rhode Island

Brasier was hooked up to dozens of electrodes, wore shoes containing 99 pressure sensors, and 40 light-reflective markers on her body were tracked by eight cameras surrounding the room to collect the data necessary for the research. She walked on the treadmill using an instrumented prosthetic leg, and again and again she tripped or slipped. Sometimes she recovered on her own and kept walking, while at other times the harness she wore saved her from tumbling.

“When we become unbalanced, our neural system reacts quickly and sends a signal to help us recover,” said He (Helen) Huang, Assistant Professor of biomedical engineering at URI, in the news release. “Our challenge is to see if we can detect these neural reactions fast enough to activate a

mechanism in a patient’s prosthetic leg to stabilize them before they fall.”

During the experimental phase of the study, Huang is collecting data from both able-bodied individuals and those using prosthetic legs to determine what kind of physiological signals can be detected for use in developing a stumble detection system. After analyzing the data, she hopes to develop an algorithm that can be used in computer-controlled artificial limbs to provide active stumble recovery.

When asked what sort of signals she might find, Dr. Huang told *OTW*, “Kinematics, kinetics, and muscle activity.”

“If we can detect the stumble reaction fast enough, then there may be time to react to it,” added Huang, who is collaborating on the project with Brown University Assistant Professor Susan D’Andrea. “Hopefully we can develop a system that can mimic the normal human reaction to stumbling.”

“We need to give a lot of credit to the patients involved in this study as they are allowing us the opportunity to collect unprecedented data related to stumble and recovery reactions in amputees,” said Michael Nunnery in the news release. Nunnery, owner of Nunnery Orthotic and Prosthetic Technologies, Inc., another partner in the research project, added, “We hope to utilize this data to have an innovative impact on the future of above knee amputee prosthetics needs.”

Brasier lost her leg when a teenage

drunk driver struck her car, an accident that took the life of her husband.

Like the other participants, she was pleased to participate in the study.

“I didn’t really know what I was getting myself into,” said Brasier in the news release. “But I’m always game for adventure. And if I can help veterans in any way, I’m glad to do it. It’s an honor.”

When asked about future research, Dr. Huang told *OTW* that the goal was to, “Develop a real-time detector to identify tripping/slipping events.

—EH (September 28, 2009) 



Marjorie Brasier, Michael Nunnery, and Dr. Helen Huang; / Courtesy University of Rhode Island

# The Picture of Success: Dr. Bernard Stulberg

By Elizabeth Hofheinz, M.Ed., M.P.H.



*Being a grandfather is awesome."*

While some might say he was fiddling around prior to his career in medicine, Dr. Bernard Stulberg, an orthopedic surgeon at the Cleveland Clinic in Ohio, knew that his interest in music was a natural part of his self discovery. Dr. Stulberg: "I was the third of four children born to a father who was a professor of violin at Western Michigan University and a mother who was a master's level nutritionist. Growing up we all played stringed instruments, which led me to enroll at Oberlin College as a performance major. It was too isolated a world for me, however, and I elected to transfer to a different environment."

Bernard Stulberg thought that he could find the right environment at the University of Michigan. "My older brother was in medical school there

and as I watched him progress, I could see that I appreciated the patient interaction and the scientific aspects of patient care."

But first, he continued on his undergraduate path of political science, which included a focus on Chinese and Russian studies. "This course of study served me well because next to politics itself, medicine is the

most political environment there is."

## Medicine and Mentors

While in medical school at the University of Chicago, Bernard Stulberg worked with Dr. Phillip Spiegel, a luminary in the AO Foundation. "Dr. Spiegel was a unique person who was known for introducing AO techniques to the U.S. He saw that I might be able to make a difference in the field and was instrumental in helping me obtain a residency at Hospital for Special Surgery (HSS)."

When he arrived in New York in 1976, Dr. Stulberg encountered an elite world of joint replacement surgery. "I was fortunate to learn from the original greats, including Dr. John Insall, Dr. Philip Wilson,

Jr., Dr. Chitranjan Ranawat, and Dr. Eduardo Salvati, among others. Dr. Wilson in particular saw the value of putting resources toward research and education in helping to ensure the field would move forward. Drs. Ranawat and Insall pushed the envelope of the emerging biomedical research arena of device development. They were very open to residents, including myself, writing articles with them, and in fact were quite cognizant of how their trainees would contribute to the field."

Staying on at HSS for his fellowship, Dr. Stulberg found a productive way to pay homage to one of his lead mentors. "Along with Dr. Fred Tria, I started the John Insall Club to honor this methodical, focused orthopedic leader. Dr. Insall would regularly ask his fellows and residents to review his results and would consistently ask us things like, 'How are we doing?' and 'Is this making a difference?' If his fellows found less successful results or if the results didn't make a difference in the way he wanted them to, he would review everything in great detail. His integrity in how he approached knee surgery was unique. Our group meets yearly to discuss various aspects of knee disease, including the evaluation and evolution of medical devices. We feel that it is a special legacy for Dr. Insall."

During his fellowship year, Dr. Stulberg was fortunate to work under the direction of a masterful researcher. "Dr. Joe Lane, head of the metabolic bone disease unit and the orthopedic service at Memorial

Sloan Kettering Cancer Center at the time, was and is a brilliant thinker. Research was already a part of my life, but as time went on, I came to further understand that research isn't something extraneous to our daily work as orthopedists...it's something that makes you a better clinician."

### Research and Development

Part of improving one's clinical—and engineering—skills, is learning to thoroughly evaluate failure: what went wrong and why. Dr. Stulberg explains, "After my fellowship I was recruited to the Cleveland Clinic by Dr. Alan Wilde, the Chair at the time, along with Dr. Lester Borden, the head of the joint replacement surgery section. In part because we had such a high volume of cases, I was fortunate to be able to start, along with Dr. Mike Manley, an implant retrieval lab."

"We had a keen interest in how devices behaved in vivo, and really wanted to learn from the patients. It was

interesting to see how collaborative of an effort this becomes. We need to know about the implant from a clinical and radiographic standpoint, and how its performance is related to the engineering concepts behind the development of the device. This sort of work is invaluable in the development and evolution of new devices. It really helps close the loop of, 'How did I design it?' 'How did it perform?' and 'What do I see in the retrieval that can help improve things going forward?'"

For Dr. Stulberg, device development can turn on one key element: proper training. The creator of three knee systems, Dr. Stulberg says, "I have come to see that the success of a device has much to do with teaching people how to properly implant a device. While device integrity does relate to the design and manufacture, most procedural failures are related to how doctors implant devices."

"Dr. Insall himself was specifically focused on how surgeons learned to use a device. If you study Sir John Charnley's introduction of the Charnley Total hip, you will see that his devices were so successful because he focused on the manner in which the devices were used, and was able to control the training of how surgeons implanted them. Thus, those he trained were expert hip surgeons. Nowadays you see parallels in the FDA mandated training of selected devices. Companies are doing a better job these days. Biomet, for example, with its mandated training for their Oxford knee, does

a wonderful job. I have participated in running Stryker's resurfacing training program, a similarly well thought out and instituted training program. I think that surgeons in general are beginning to get better training on the devices. Keep in mind that as we develop increasingly sophisticated products we will need more and improved training."

Fascinated with how bone changes in response to different implants and environments, in the early '80s Dr. Stulberg took his investigations to the laboratory. "I was fortunate that Cleveland Clinic had just begun a program for funding research which eventually helped me obtain a grant from the Orthopaedic Research and Educational Foundation to investigate bone remodeling around uncemented implants. This was the time when there was an explosion of uncemented arthroplasty and it was the thing for young investigators."

"Along with Dr. Tom Bauer, we began tissue and implant retrievals to look at how the bone environment influences the success of the implants and the procedure to implant them. In addition to assessing techniques of undecalcified bone sectioning, we helped develop the application of bone densitometric evaluation (DEXA scanning) to the in-vivo measurement of bone remodeling around implants. This process, now widely used, helps to see whether the design goals you have evolved in the implant achieve the desired effect in vivo."

### Going Solo

During his 15 years spent in private practice, Dr. Stulberg learned how to

advertisement

blend brisk efficiency with a personal touch. “I left the Cleveland Clinic in 1990 to work at Case Western Reserve University, but left after two years to start a private practice. During the 15 years of solo practice I continued to work with Dr. Bauer in the form of a combined sponsorship of an international fellowship with several Japanese centers. As time progressed I also became intrigued by the business side of medicine and the delivery of healthcare. I was especially interested in high volume practices that can deliver a patient friendly product. Such environments are necessarily very collaborative, and the surgeon must be intimately involved in making it work. Running the back office ‘like a machine’ does not exclude the possibility of providing a highly personal patient-friendly environment. I was particularly influenced by the efforts of Dr. Thomas Mallory, whose organizational genius has influenced many of the joint replacement centers around the US.”

“I returned to the Cleveland Clinic in May 2008, in part because my partner retired, but also because healthcare in Northeast Ohio has become less friendly to private practices. I also have had an opportunity to consult with Exactech, something that has been stimulating and great fun. This is particularly true because I get to work with Dr. Al Burstein, one of my mentors from HSS, as well as Drs David Covall, Jay Maybrey, and the entire design team at Exactech. We have developed a variation of their prior knee design to specifically address consistency in the placement of cruciate retaining TKA devices.”

### A Born Leader

Having grown as a leader and grown leaders over the years, Dr. Stulberg is keen on the idea of professional level leadership. “I personally believe that leadership is developed in those who have the talent and vision to lead, and is not something everyone is comfortable with. I have had two particular experiences that have helped shaped my opinions/vision of leadership.”

“During my time in private practice, my program, the Cleveland Center for Joint Reconstruction, Inc., became the first joint replacement practice in the world and the first medical practice in the U.S. to embrace the tenets of customer-focused and transparent health care, and became certified to ISO9001 performance standards in 1995. We were a small group, and the behavior of

all involved was appropriately focused. The effort, however, was led by my nurse manager at the time and by a business expert who co-managed the program and had successfully implemented ISO9001 in 6 different businesses. My role as leader was to step back, support the effort, and submit to the group-driven behavior.”

But sometimes leading involves stepping forward and taking charge. Dr. Stulberg had the opportunity (as Chairman of the AAOS’s Committee on Biomedical Engineering) to organize and oversee an expansive effort to ensure the safety and efficacy of orthopedic devices. “I am proud to have led the Orthopaedic Device Forum, a collaborative effort of the American Orthopaedic Association (AOA), the American Academy of Orthopaedic Surgeons (AAOS), Orthopaedic Manufacturers Association and the Orthopaedic Research Society.”

“This project brought together academicians, leaders of industry and research and clinical scientists to facilitate product development and to increase the availability of products to patients in the U.S. The primary focus was on collaborating and facilitating interactions with these groups and with the appropriate regulatory programs within the FDA. In that effort I had the opportunity to work with orthopedic industry leaders such as Dane Miller, Ph.D. (Biomet) and Jack Parr Ph.D. (Wright Medical), as well as many other very responsible individuals from industry.”

“Also part of this Forum,” says Dr. Stulberg, “were major leaders of our research community, such as Drs.



advertisement

Barbara Boyan, Timothy Wright, Jack Lemons and Seth Greenwald, and leading clinicians of the AOA and AAOS. Each of these individuals, leaders in their own environments, recognized the importance of leaving their respective biases ‘at the door’ and working collaboratively for the common goal of making safe and effective new products available to the American public. What was accomplished during the 10 years I worked with this group was truly remarkable and inspiring. The efforts continue today under the excellent leadership of Dr. Michael Yaszemski, M.D., Ph.D.”

But despite his grand accomplishments in the world of doctors and researchers, Bernard Stulberg finds

his most meaningful times with another group—the Stulberg clan. “The luckiest moment of my life was when I met my future wife, Carolyn. In our 33 years of marriage she has helped me achieve a balance of family and work that has allowed us to raise four terrific boys, all who have now moved toward careers and lives of their own. In fact, as of August, we have two grandsons. The family loves being together, whether supporting The Stulberg International String Competition, founded in memory of my parents by many of my father’s students, or pursuing outdoor activities such as boating, skiing, running, or soccer. We are known for large family gatherings...to the point where my close friend and colleague

Dr. Bill Bargar and his wife Carol have noted, ‘the Stulbergs don’t travel, they herd.’ It has been and continues to be a wonderful journey together.”

Dr. Bernard Stulberg...closing the research loop and opening doors for future generations.



# Quality...



Rachel Frank, allograft meniscus recipient and Research Fellow in Orthopedics, Rush University Medical Center. 2009 Hawaii Ironman 70.3 Triathlon Finisher.

From donor recovery to allograft distribution, AlloSource maintains a rigorous quality assurance process. We focus on allograft quality and safety so you can focus on patient care.



**AlloSource**  
Delivering Powerful Possibilities™

**AlloSource**  
6276 South Troy Circle  
Centennial, Colorado 80111  
Tel Free 800 557 3587  
[www.allosource.org](http://www.allosource.org)

## that you can depend on.

advertisement

## Orthopedics This Week | RRY Publications LLC

**Robin R. Young, CFA**  
Editor and Publisher  
robin@ryortho.com

**Elizabeth Hofheinz, M.P.H., M.Ed.**  
Senior Writer  
elizabeth@ryortho.com

**Walter Eisner**  
Senior Writer  
walter@ryortho.com

**Tom Bishow**  
Vice President of Sales  
tom@ryortho.com

**Julia Cecil**  
Marketing & Promotions  
julia@ryortho.com

**Suzanne Kirchner**  
Production Manager  
suzanne@ryortho.com

**Jayne Johnson**  
Production Coordinator  
jayme@ryortho.com

**Eileen Mesi**  
Creative Director  
Red Line Design  
eileen@ryortho.com

### Main Contact Information:

**RRY Publications LLC**  
116 Ivywood Lane • Wayne, PA 19087  
TOLL FREE: 1-877-817-6450  
Fax: 610-260-6451



Don't miss your chance!  
Advertise with Orthopedics This Week

Orthopedics This Week

Click Here for more details or email [tom@ryortho.com](mailto:tom@ryortho.com)  
Tom Bishow | 410.356.2455 (office) or 410.608.1697 (cell)