

Orthopedics • This Week

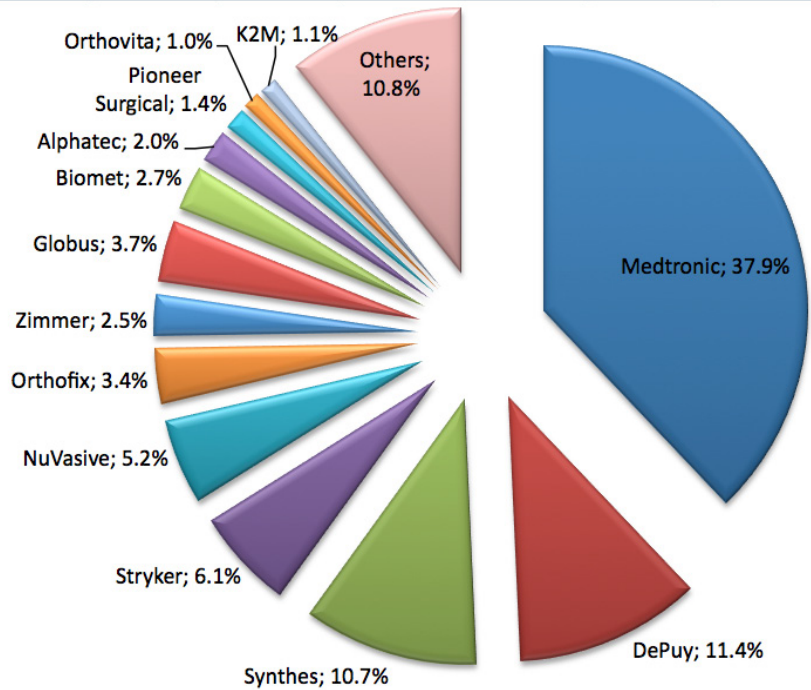
week in review

4 Medtronic Spine Staggered ♦ Medtronic lost 4.7% of market share in spine this last quarter. Revenue declined over 9%. What happened? The company's CEO Bill Hawkins acknowledged the pain and said people won't defer procedures forever and Medtronic will be back. How will they do it? Read here.

9 Recon Sales Growth Slowing ♦ The large joint reconstruction market slowed following two quarters of strong growth. Read on to find out how both foreign and domestic sales descended back toward the ground level.

14 Here Come Orthopedic Bionics ♦ Bionics prosthetics are one of those high-profile scientific developments that seem to capture our imagination and elicit "ooohs" and "aaahs." See how one company, Scotland's Touch Bionics, is tackling the task of making robotic arms more human-like and ultimately, more useful.

18 The Future of Spine Is Here: SERC ♦ State-of-the-art only begins to describe the NASS Spine Education and Research Center. A 3,800 sq. ft. bio-skills lab with 12 fully equipped work stations, and the ability to stream content worldwide, means a superb learning environment.



picture of success

31 Jeffrey N. Katz, M.D., MSc ♦ Dr. Jeffrey Katz, Director of the Orthopaedics and Arthritis Center for Outcomes Research at Brigham and Women's Hospital, is a prolific researcher who says that patients are good teachers...and that doctors must be good students.



breaking news

- 22 Rotten Eggs and Rotten Knees**
- KineGraph Study: Finding the Right Patient**
- Gender Knee Study Draws Attention**
- Protein Helps Titanium Implants Stick**
- Orphan Drug OK for BioMimetic**
- Stryker Buys Gaymar for \$150 Million**
- SI-BONE Closes on \$11 Million**

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthopedic valuations have fallen so far they have moved beyond cheap to existential. Medtronic, who has been losing spine market share for three years, reported that the decline is accelerating. Alphatec, which is digesting its Scient'x purchase is off 50% to literally pocket change per share. Last time ATEC came down this far, the stock rebounded like a super ball. The bargains are everywhere in ortho.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.51%	(5.06)%	OFIX has been #1 longer than any other company. Why? Best cash flow for the \$ in all of ortho.
2	3	Kensey Nash	38.72	11.69	Speaking of cash—investors made 12% on KNSY in the last 30 days. This is KNSY's market.
3	4	Johnson & Johnson	27.10	0.07	You know, business cycles come and go but healthcare is a constant. That and JNJ's exorbitant dividend yield—3.7%
4	2	Integra LifeSciences	15.37	2.55	Brain catheter recall doesn't help. But Stu and the team keep beating Street estimates.
5	NR	Alphatec	1.59	(51.25)	CEO Kuyper just bought a slug of stock. At these prices, he likes to own his own company. We agree.
6	6	CONMED	8.76	4.54	This little Utica, New York-based company keeps outperforming the big guys—and posting record profits.
7	7	Smith & Nephew	22.83	(2.07)	Not as beaten down as its Warsaw (Indiana) brethren, SNN has proved to be much less volatile than SYK or ZMH.
8	9	Stryker	24.71	(7.35)	Yes, SYK is clearly oversold and is now the 7th least expensive company in orthopedics.
9	8	Zimmer	27.69	(10.88)	Speaking of existential, the travails of ZMH must remind Dvorak of a Camus novel. Now MDT's troubles affecting Big Blue.
10	5	Medtronic	32.48	(13.02)	Ok, unexpectedly poor results but, in the trenches, among surgeons MDT is starting to come back. It'll just take time.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Osteotech	OSTE	\$6.40	\$116	80.8%
2 Capstone Therapeutics	CAPS	\$0.92	\$38	19.5%
3 Kensey Nash	KNSY	\$26.57	\$259	11.7%
4 TranS1	TSON	\$2.49	\$52	7.3%
5 CONMED	CNMD	\$19.11	\$550	4.5%
6 Integra LifeSciences	IART	\$36.19	\$1,050	2.6%
7 Johnson & Johnson	JNJ	\$57.60	158,660	0.1%
8 Smith & Nephew	SNN	\$42.03	\$7,470	-2.1%
9 Average			\$10,334	-3.5%
10 ArthroCare	ARTC	\$25.90	\$700	-4.3%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Alphatec Holdings	ATEC	\$2.14	\$187	-51.3%
2 RTI Biologics Inc	RTIX	\$2.20	\$121	-27.2%
3 Wright Medical	WMGI	\$13.71	\$538	-14.0%
4 Symmetry Medical	SMA	\$9.12	\$328	-13.9%
5 Medtronic	MDT	\$32.52	35,220	-13.0%
6 Mako Surgical	MAKO	\$10.58	\$358	-11.7%
7 Zimmer Holdings	ZMH	\$48.01	\$9,650	-10.9%
8 Orthovita	VITA	\$1.70	\$131	-10.5%
9 NuVasive	NUVA	\$30.48	\$1,200	-10.5%
10 Stryker	SYK	\$44.00	\$17,470	-7.3%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Medtronic	MDT	\$32.52	\$35,220	9.71
2 Zimmer Holdings	ZMH	\$48.01	\$9,650	11.43
3 Kensey Nash	KNSY	\$26.57	\$259	11.83
4 Wright Medical	WMGI	\$13.71	\$538	12.06
5 Average			\$10,334	12.13

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Smith & Nephew	SNN	\$42.03	\$7,470	57.88
2 Synthes	SYST.VX	\$109.73	\$13,023	30.67
3 RTI Biologics Inc	RTIX	\$2.20	\$121	28.77
4 NuVasive	NUVA	\$30.48	\$1,200	25.04
5 Symmetry Medical	SMA	\$9.12	\$328	23.82

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 NuVasive	NUVA	\$30.48	\$1,200	0.60
2 Orthofix	OFIX	\$28.14	\$496	0.61
3 Exactech	EXAC	\$15.13	\$195	0.70
4 Smith & Nephew	SNN	\$42.03	\$7,470	1.00
5 Medtronic	MDT	\$32.52	\$35,220	1.05

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 CONMED	CNMD	\$19.11	\$550	14.30
2 Johnson & Johnson	JNJ	\$57.60	158,660	1.90
3 Average			\$10,334	1.66
4 Symmetry Medical	SMA	\$9.12	\$328	1.59
5 Alphatec Holdings	ATEC	\$2.14	\$187	1.57

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 RTI Biologics Inc	RTIX	\$2.20	\$121	0.73
2 CONMED	CNMD	\$19.11	\$550	0.76
3 Orthofix	OFIX	\$28.14	\$496	0.88
4 Symmetry Medical	SMA	\$9.12	\$328	0.97
5 Exactech	EXAC	\$15.13	\$195	1.04

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$2.07	\$64	228.37
2 Mako Surgical	MAKO	\$10.58	\$358	10.81
3 Synthes	SYST.VX	\$109.73	\$13,023	7.22
4 Kensey Nash	KNSY	\$26.57	\$259	3.26
5 NuVasive	NUVA	\$30.48	\$1,200	2.79

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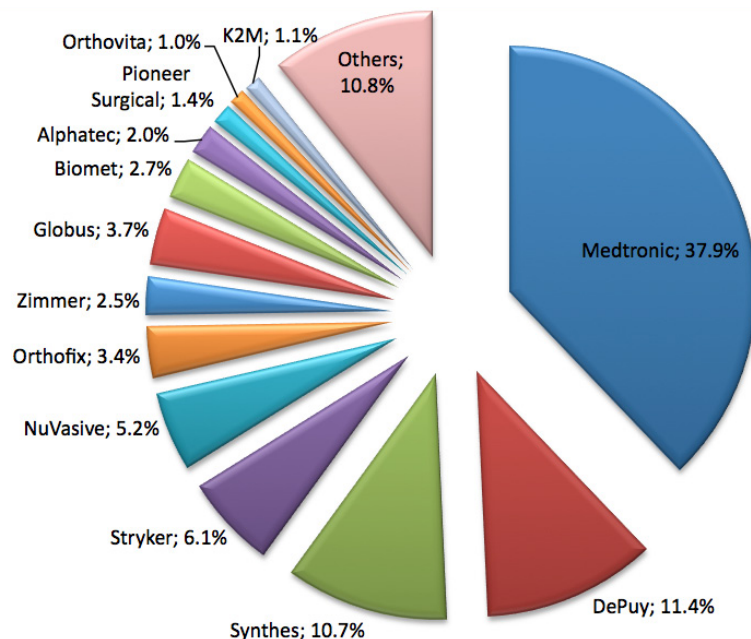

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Medtronic Spine Staggers

By Walter Eisner



PearlDiver Technology, Inc.

Surprised, confused and unexpected aren't terms surgeons, patients and investors like hearing from their medical device makers.

But those are some of the words Medtronic CEO Bill Hawkins used during a conference call with analysts on August 24 to describe the world's largest spine device maker's horrible quarter. Spine sales dropped over 9%.

This is a big admission from the ailing 800-pound Gorilla of spine.

Spine sales of \$829 million for the quarter were down over 9%. Biologics, including InFuse, were down 5%. Spine hardware was down almost 7% and Kyphon, which Medtronic purchased for \$4 billion a couple of years ago, was down over 20%. Overall, Medtronic's sales were down 4%.

Shifting Corporate Culture?

The fact that Medtronic is based in Minnesota, home of 10,000 12-step recovery programs, may have something to do with Hawkins' admission of problems. Perhaps we are seeing a shift in the company's culture. In the past year Medtronic has become the first spine company to voluntarily disclose payments to surgeons. Senior executives have openly admitted to overpaying for Kyphon. Hawkins shuffled spine leadership and then stepped up to buy Osteotech at a good price.

These are things we might not have seen from Medtronic's spine division in Memphis a few years ago.

Fewer Jobs, Fewer Procedures and Price Squeezing

So what happened since the company met with analysts in March and painted a rosy picture for the future?

Hawkins pointed to a "challenging environment." He told analysts that a high unemployment rate and higher insurance costs have cut down on doctors' visits and hospitals have been squeezing manufacturers on pricing.

"I think that we are just in this kind of transition phase as we are trying to figure out what is going to happen long-term with the economy," Hawkins told analysts. "I am confident that we



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Bill Hawkins

will get through this and that people will return to going to see the doctor.”

Declining Market Share

Wells Fargo analyst Mike Matson estimates Medtronic lost 4.7% of spine market share during the quarter, while the cheetah, NuVasive, gained 1.3%.

Hawkins said the biggest surprise for the company was the magnitude of the market slowdown and that slowdown escalated in late June and through July. The company saw per-procedure revenues decline driven by changes in product mix.

Refreshing Portfolio

“We remain focused on refreshing our entire [spinal] product portfolio. Solera, which is in its limited release phase, together with the recently launched TSRH 3Dx, are receiving very positive surgeon feedback.

“In biologics, we were encouraged by the positive FDA advisory panel recommendation for Amplify, and anticipate approval later this fiscal year.

“We continue to supplement our organic innovation and growth with

tuck-in acquisitions that leverage our broad global footprint. Last week we announced our agreement to acquire Osteotech, which will enhance our strong portfolio of biologic products by adding best in class DBMs, consistent with our strategy of expanding our portfolio in the very attractive biologics market.”

Was this just “happy talk” from Hawkins and what are the challenges facing Medtronic as the company tries to stabilize spine sales?



Matt Menze, PearlDiver Senior Spine Analyst

Matt Menze, senior PearlDiver spine analyst told OTW that Medtronic is right to focus on new product launches and quantitatively showing how these products save on costs.

“However, during the call,” said Menze, “it was suggested that in order to save on costs, some hospitals are shifting back to titanium and away from PEEK. PEEK is part of some of the new products Medtronic is developing and for which it is hoping to receive premium pricing. The burden will be on Medtronic to show that the premiums are warranted.”

Spine Surgery Pushback

Menze noted that Hawkins indicated that the company was seeing private payer pushback regarding indications for spine surgery as well.

“Indications such as ‘lumbago’ or ‘low back pain’ are drawing scrutiny from insurers,” said Menze.

PearlDiver Dissects the Codes

“We queried the PearlDiver private pay database and analyzed 7,061 posterior lumbar fusions performed in 2009. We found that ‘back pain’ (as defined by ICD-9 diagnosis code 724.5) was coded in 2.5% (178 procedures) of the cases. Lumbago (as defined by ICD-9 diagnosis code 724.2) was coded for 12.5% (886 procedures) of the cases.

“‘Back pain’ was coded as the primary diagnosis (or the diagnosis most related to the

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procedure) in under 1% of the cases, while lumbago was coded as primary diagnosis in 196 procedures or 2.7% of the cases.”

This, according to Menze, means that 1-3% of posterior lumbar spine fusions are “at risk” for private payer pushback due to back pain being the diagnosis, while about 12% are at risk due to a diagnosis of lumbago. Overall, Menze said these account for the minority of cases.

“However, lumbar DDD—degenerative disc disease—as defined by ICD-9 diagnosis code 722.52) was coded in 58% or 4,088 cases. It would seem that the larger threat

would be if private insurers began requiring something more than DDD as a diagnosis, such as spinal instability since DDD comprises the majority of posterior lumbar spine fusion cases,” concluded Menze.

Hawkins told analysts that lower back pain is the second most common reason people go to see a physician and the number of people who are actually getting instrumented through fusions or having a surgical operation is still a very small percent. “I think as the technology continues to evolve, as we advance more minimally invasive approaches, whether it’s the direct lateral approach or whether using some of the navigation technologies that we have, I believe we’re going to be able to continue to grow the overall market.”

New Targeted Products

Hawkins believes new products, beginning with Solera, the TSRH 3Dx, Vertex Select and whole series of products are “targeted right at where the market is going, so we’re optimistic over the long run, but we’re in a period now that is a bit uncertain.”

Gary Ellis, Medtronic’s CFO told analysts that netting out the effect of the market slowdown during the quarter, Medtronic performed about where management expected relative to the market “as we continue to progress toward returning the business to market growth by the end of FY11.”

“However, based on current market conditions, we believe that it is more reasonable to model flat FY11 revenue growth for our spinal business, which includes the negative impact of the extra week last year and assumes spine market growth for the remainder of our fiscal year of 3% to 4%.

Flat, Negative 2010

PearlDiver’s Menze was not as optimistic. Menze said he anticipates flat to slightly negative revenue growth for calendar year 2010.

He estimates third quarter revenues will decline 3.7% resulting in \$830 million in sales. He expects calendar year 2010 revenues to decline 1.9% to \$3.434 billion.

“After including Medtronic results into our overall market model, we estimate that overall spine market growth was slightly negative for the quarter. We do not anticipate that there will be a reversal of the negative trends affecting the spine market by year end.

“There are also macroeconomic signs indicating that the economic recovery (if there is one) may not be as robust as previously thought. High unemployment resulting in a loss of benefits is key, as 70% of spine fusions are covered by private insurers and the majority of patients that are privately insured receive their health insurance through their employers. The industry faces sever macroeconomic headwinds and industry specific challenges.”

Reducing Spine Exposure

Menze observed, “Management indicated that the company is working to develop an overall portfolio that is less leveraged to spine (22% of Medtronic’s total revenue is spine related). This indicates that the company does not view spine as making the strong contribution to overall company revenue growth as it did in the past.”

Perhaps this is another sign of a culture shift at Medtronic. Is this quarter the handwriting on the wall that Medtronic is accepting a loss of market share to competitors? Could it be a sign of Lukianov’s revenge?

Hawkins didn’t appear to reflect that sentiment.

Navigating a Mega Trend

Hawkins described a “mega trend” with hospitals purchasing more physician practices. The hospitals are working to get their physicians to look at ways to reduce those costs without compromising patient care.

“That puts the onus back on us to be able to clearly demonstrate that when we bring out PEEK materials there is very clear evidence to support the

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clinical benefit of using a different material versus, say, a titanium.

“We’re investing a lot in clinical evidence. The number of clinical studies we have across the enterprise, I think, is unparalleled in the industry.”

The company is on pace to spend over \$1.2 billion in R&D alone this fiscal year.

China, India, Brazil

Hawkins is also looking overseas.

“Four or five years ago,” said Hawkins, “we invested in China. I was there two weeks ago and I couldn’t be more enthusiastic about the long-term prospects for where China is. It’s close to a half a billion dollars run rate right now and growing at 20% plus a quarter.

“So we’re making those investments and we have been in the other markets like India and Brazil. We’re confident that these are going to be strong markets over the long run.

Will the Gorilla recover and find his legs and hold off the Cheetah? ♦



Flags of China, India, and Brazil/ Wikimedia Commons

Recon Heading Back Toward Ground?

By Scott Ellison, PearlDiver Large Joint Reconstruction Senior Analyst

Large joint reconstruction industry suppliers sold \$2.9 billion of products in the second quarter (2Q10), falling just short of our forecast of \$3.0 billion. We have, therefore, held our forecast for the large joint reconstruction industry at \$3 billion for the 3Q10. We have slightly decreased our forecast for the year from \$12.2 billion to \$12.04 billion, primarily reflecting the second quarter results.

One year ago at this time reported sales from companies supplying large joint reconstruction implants and instruments were actually declining year to year (down 4.2%). Of all the suppliers reporting last year, only Biomet and Exactech posted mid-year sales gains, and in knees Biomet stood alone. Finally, for the second half of 2009, sales of large joint recon products rebounded nicely and posted a respectable 8% rate of sales growth for those last two quarters of 2009.

For the second quarter of 2010, large joint recon sales rose 4.5% which is actually a slower rate of sales growth than the final quarters of 2009, but clearly stronger than the same quarter in 2009. At the one-year mark sales growth is clearly in positive territory but it is moderating from the rebounding growth rates of the end of last year. Here are some highlights from the second quarter sales reports for large joint recon sales:

- Sales growth rates outside the U.S. (OUS) were stable but less than those of the first quarter



GSDf parachute/Wikimedia Commons

- U.S. sales growth rates were mixed
- Pricing pressure continues to weigh on revenue growth rates

Manufacturers of large joint recon implants and instruments reported that aggregate sales rose 4.5% year-over-year (YOY) as illustrated in Chart 1. Sales of both hip reconstruction and knee reconstruction products grew although sales of knee products rose 4.8% YOY which outpaced sales of hip products (up 4.3% YOY) for the fourth consecutive quarter.

The Slow Down

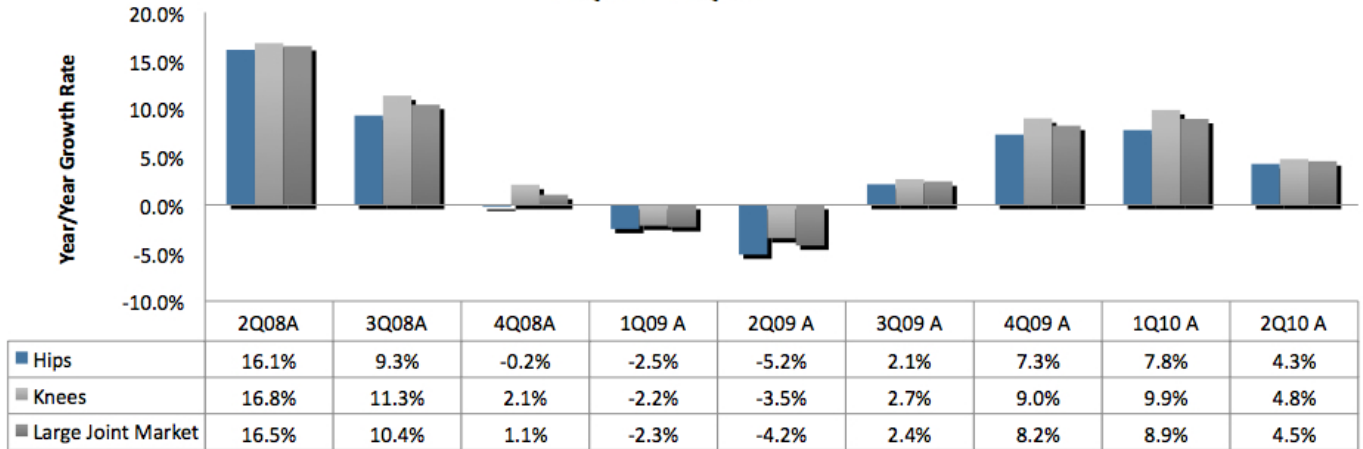
As Chart 1 illustrates, industry sales growth rates had rebounded during

the fourth quarter of 2009 and the first quarter of 2010. In prior quarters revenues had actually declined from year-earlier levels. Now sales growth rates of large joint products appear to be slowing again.

At this time a year ago, unstable OUS sales were at the core of overall large joint product revenue declines. During the second quarter of 2009, all three of the market leaders in large joint reconstruction reported that sales of hip, knee or both products had declined from prior year levels. Zimmer, the market leader, reported that its sales of hip products fell 14.9% outside the U.S. and that its knee products were down 11.2%.

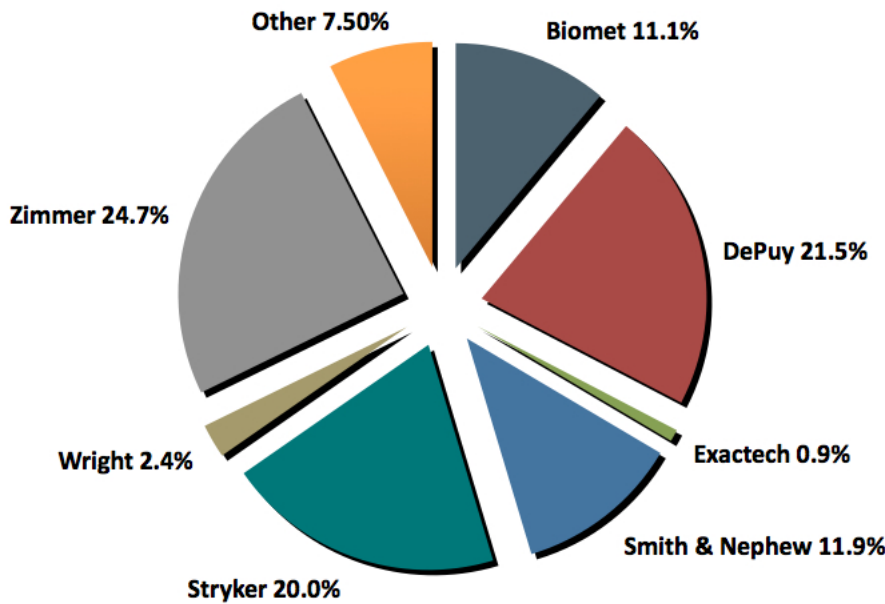
Chart 1: Large Joint Reconstruction Market Revenue Growth (YOY)

**Large Joint Recon Revenue Growth Rate
2Q08 - 2Q10**



Source: Company Reports

Chart 2: Large Joint Reconstruction Market Share as of 2Q10



Source: Company Reports

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Better markets for U.S. large joint recon products outside the U.S., not surprisingly, were also at the core of the sales growth rebound during 4Q09 and 1Q10. In the fourth quarter of 2009, Zimmer reported a 9.8% YOY increase in OUS hip sales and a 17% increase in OUS knees. Stryker also had impressive gains with a 13% YOY increase in both OUS hips and OUS knees. The first quarter of 2010 showed similar OUS results—Zimmer hips increased 7.0%, Zimmer knees 14.4%, and Stryker hips and knees 11%. We believe DePuy's OUS sales lagged their competitors by one quarter, and in the first quarter of 2010 rose by 6% in OUS hip sales and 8% in OUS knee sales.

But of course this story doesn't end in the first quarter. The good news with OUS sales revenues is that the top two producers by market share as shown in Chart 2, Zimmer and DePuy, continued to report that sales of hip and knee products continue to grow outside the U.S. For the 1Q10 Zimmer reported that its OUS large joint recon sales rose 2.4% in hips and 4.2% in knees while, we estimate, DePuy managed

to increase its OUS hip sales by 3.7% and knees by 3%. Stryker, #3 in market share, reported that OUS sales increased 4% in hips but declined 5% in knees.

For U.S. sales, Zimmer clearly had strong results to report. For the 2Q10 Zimmer posted a 3.5% rate of hip sales increase which was the same rate as 1Q10, and a 2.9% rate of sales increase for knees which was lower than the 3.6% reported growth in the first quarter of 2010. Stryker also posted large joint sales increases at a rate which was below those in the first quarter of 2010. In Stryker's second quarter, sales of hip implant products rose 2% YOY, down quite a bit from the first quarter's 7% rate of hip sales growth. Sales of Stryker knee implants rose 4% in the second quarter, which was a much slower rate of growth than the 12% Stryker reported in 1Q10.

Pricing pressures are clearly the #1 cause of these sluggish revenue growth rates. According to Catherine Owen, Stryker's Vice President of Strategy, "We're not seeing anything different on the pricing trends in terms of the pricing pressure that existed in the recon market." Price cuts in Japan did impact large joint recon sales, especially knees according to David Dvorak, Zimmer's Chief Executive Officer.

Quarter by Company

Biomet, Inc.

Biomet, Inc. reported that it sold \$371.3 million of large joint reconstruction products in its May quarter (which is Biomet's fourth quarter of

2010), up 13.0% YOY. That rate of growth was the highest of all major large joint implant companies. Biomet's hip repair product sales increased 10.0% YOY to \$148.2 million, in line with PearlDiver expectations. Knee repair product sales increased 15.0% to 223.1 million, also in line with PearlDiver expectations.

DePuy, Inc. (a Johnson & Johnson company)

DePuy, Inc., we estimate, sold \$667.8 million of large joint reconstruction products, up 5.8% increase from 2Q09. Hip repair product sales, we estimate, increased YOY by 6.4% to \$291.5 million. We attribute the success to product mix and newer products such as the ASPHERE Contoured Metal Head and continued use of the traditional Pinnacle Hip Solutions.

DePuy reported that knee repair product sales increased 5.4% to \$376.6 million YOY. We also attribute this success to the strength of the underlying business and sales from the Sigma Knee Portfolio.

Stryker, Inc.

Stryker, Inc. reported low rates of YOY revenue growth rates for both hip and knee reconstruction markets. Overall, company officials reported that sales of large joint repair product sales rose 1.7% to \$592.1 million. Stryker's hip repair product sales increased 2.9% YOY to \$285.2 million while its knee repair product revenues increased 0.5% to \$306.9 million. Both hips and knees were well below PearlDiver and Wall Street expectations due to unexpected slower performance in the U.S. and continued slow rates of sales growth in Europe.



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Zimmer, Inc.

Zimmer, Inc. reported that its large joint reconstruction sales rose 3.3% YOY to \$770.2 million, which was in line with PearlDiver expectations. Hip repair product sales rose 3.0% to \$317.2 million led by Fitmore and M/L taper sales. Knee repair products increased 3.5% to \$453 million with the help of patient-specific instruments.

Looking Forward

Looking ahead, there are several factors which we anticipate will have a positive impact on sales growth rates in the second half of 2010. First, while the growth rates were not as impressive as the first quarter of 2010, there is a returning sense of stability to growth rates.



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Additionally, a number of new products are expected to have a positive impact. For example, the continuing rollout of Stryker's ADMX3 hip system, the Zimmer Continuum Cup Hip System, and Wright Medical's Evolution Medial Pivot Knee System.

With these reasons in mind, we are forecasting the following performance for large joint recon sales in the current quarter:

- Sales of large joint recon products will likely rise 7.0% YOY
- Sales of hip recon products will likely increase 5.7% YOY
- Sales of knee recon products will likely rise 8.1% YOY

- Gains on a per company basis are shown in Table 1



Table 1: Forecasted Hip and Knee Repair Revenues

	2Q10 A	3Q10 E	2010 E	2011 E	2012 E
Zimmer	\$770.2	\$731.6	\$3,162.5	\$3,281.2	\$3,441.8
Hips	\$317.2	\$293.8	\$1,275.1	\$1,318.3	\$1,371.0
Knees	\$453.0	\$437.9	\$1,887.4	\$1,962.9	\$2,070.8
DePuy	\$667.8	\$695.1	\$2,833.5	\$3,041.8	\$3,227.2
Hips	\$291.5	\$316.7	\$1,300.6	\$1,378.6	\$1,447.6
Knees	\$376.3	\$378.4	\$1,532.9	\$1,663.2	\$1,779.6
Stryker	\$592.1	\$639.1	\$2,592.2	\$2,800.3	\$2,990.7
Hips	\$285.2	\$301.5	\$1,216.0	\$1,307.2	\$1,385.6
Knees	\$306.9	\$337.6	\$1,376.1	\$1,493.1	\$1,605.1
Smith & Nephew	\$362.1	\$360.6	\$1,532.4	\$1,734.4	\$1,891.6
Hips	\$167.4	\$171.4	\$717.6	\$811.0	\$875.9
Knees	\$194.7	\$189.2	\$814.8	\$923.4	\$1,015.7
Biomet*	\$371.3	\$369.8	\$1,491.9	\$1,579.5	\$1,703.0
Hips	\$148.2	\$147.9	\$603.4	\$627.5	\$657.3
Knees	\$223.1	\$221.9	\$888.5	\$951.9	\$1,045.7
Wright	\$76.0	\$75.4	\$318.7	\$335.1	\$357.6
Hips	\$44.2	\$42.9	\$185.5	\$194.3	\$206.9
Knees	\$31.8	\$32.5	\$133.2	\$140.8	\$150.7
Exactech	\$26.7	\$26.3	\$111.3	\$116.7	\$120.1
Hips	\$7.3	\$7.3	\$29.3	\$30.2	\$27.7
Knees	\$19.4	\$19.0	\$82.0	\$86.5	\$92.4
Total	\$2,866.1	\$2,897.9	\$12,042.5	\$12,889.1	\$13,732.1
Hips	\$1,261.1	\$1,281.4	\$5,327.5	\$5,667.2	\$5,972.1
Knees	\$1,605.1	\$1,616.5	\$6,715.0	\$7,221.9	\$7,760.0

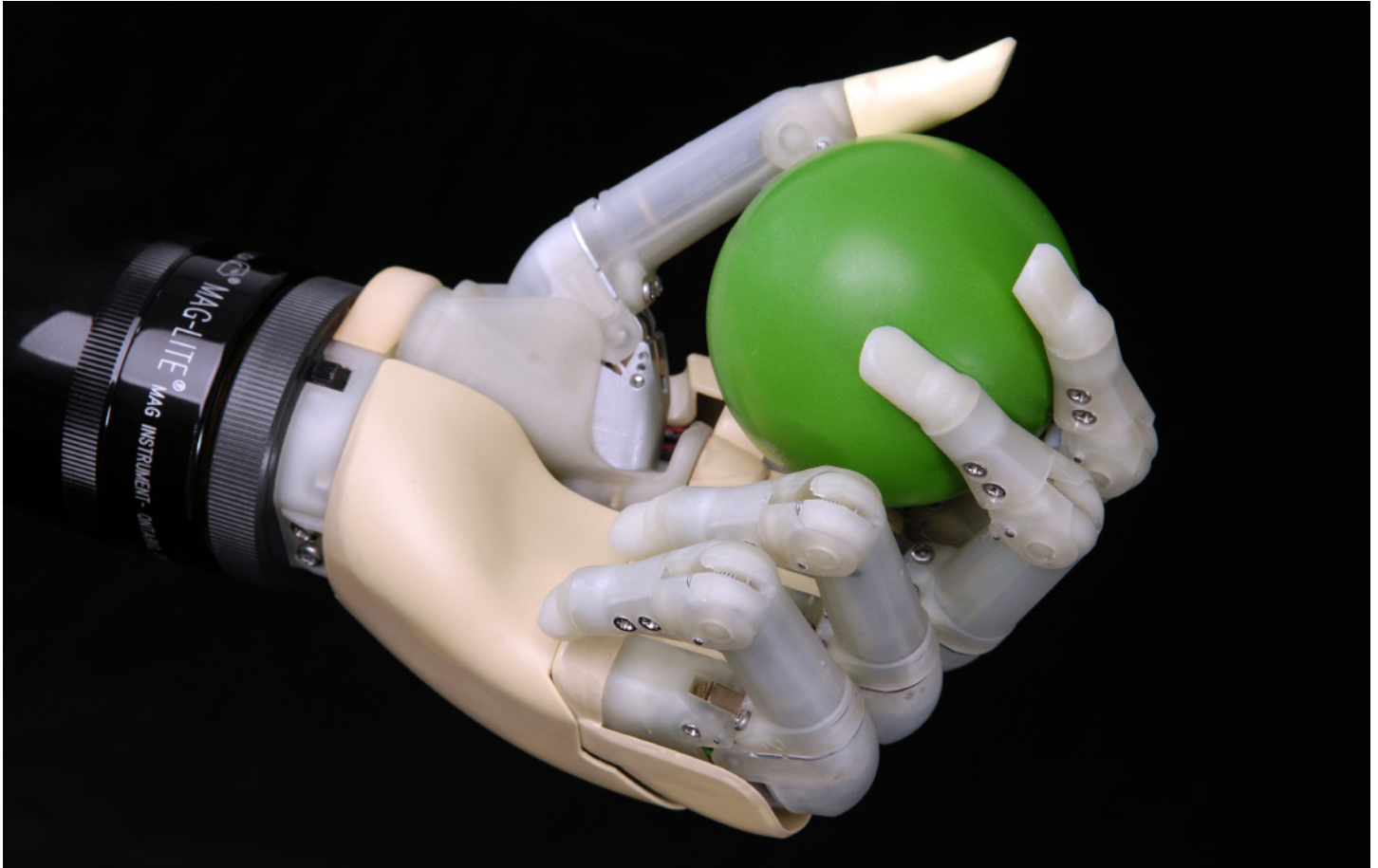
* adjusted to match fiscal year of Jan 1 to Dec 31

Source: Company reports

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Here Come Orthopedic Bionics

By Jacqueline Rupp.



i-Limb Hand/Touch Bionics

Think of all the tasks we use our hands for each day. From shutting off the alarm clock in the morning to brushing our teeth before bed and everything in between, our hands and fingers manipulate our world. What would your life be without them?

For patients missing digits or arms, bionic prosthetics are finally delivering close-to-normal functionality. These new generation prosthetics have fingers that move and grip, wrists that gracefully turn and true-to-life artificial

skin. It's increasingly hard for the casual observer to tell these devices apart from the real thing.

Combining orthopedics with engineering and adding in a sprinkling of science fiction, bionic limbs are the startlingly tangible representations of how well developers have re-created and re-interpreted living bone, muscle and sinew. These new generation bionic limbs are astonishing but also practical as they literally give patients a better way to live.

Who Are These Guys?

Three firms appear to be bionic technology leaders:

- RSLSteeper, which offers the bebionic fully-articulating myoelectric hand
- DEKA Research and Development Corporation, a New Hampshire company that grabbed headlines a few years back with its bionic hand affectionately dubbed "Luke" in honor of the prosthetic-wearing Star Wars hero



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- Touch Bionics Ltd, the seven-year-old privately held developer and marketer of upper-limb prosthetics headquartered in Livingston, Scotland (formerly known as Touch EMAS Ltd). Touch was just awarded the Most Innovative Company of the Year in Europe award at the 2010 International Business Awards program.

Academia has also been in on the act, with the U.S. Armed Forces lending a hand to the tune of \$100 million in grant funding. The Johns Hopkins Applied Physics Laboratory in North Laurel, Maryland, for instance, is developing prosthetic devices which use brain signals to direct and control artificial limbs.

Touch Bionics's two principal products are i-LIMB Hand, a multi-articulating myoelectric bionic hand (which uses signals from a residual limb to pick up and interpret voluntarily contracted muscle signals) and ProDigits, individually powered fingers, with myoelectrical controls and full articulation.

Mark Ford, VP of North American operations at Touch Bionics, says that his company is the global leader in upper limb prosthetics with more than 1,200 i-LIMB Hands in use. Furthermore, Touch Bionics is the only provider of externally powered prosthetic devices for partial hand amputees. "From my perspective, the journey has been amazing. To take a prototype design of a completely new prosthetic technology and turn it into a successful, rapidly growing company is remarkable in and of itself. To make those leaps in less than seven years, and during a global recession, is even more astounding."

"Have You Been 'Touched?'"

That's the catch phrase around Touch Bionics. It refers to the dramatic effect these new generation bionic prosthetics have on patients, patients' families, doctors and, yes, the engineers and staff at Touch Bionics.

Says Ford: "The reality is that our innovations really do change the lives of people around the globe, and those changes can be obvious, marked revolutions for our patients. When members of our team regularly see their individual work lead to a dramatic improvement in another human being's life, it becomes very easy to become committed to the mission of Touch Bionics."

Ford adds the company has several new products in its pipeline including some new upper limb prosthetic offerings. "This product development work will include continuing to develop the functional patient benefits of the i-LIMB Hand and ProDigits system, improving the clinical intake processes for our LIVINGSKIN functional aesthetic product line, and developing a systematic, patient care follow-up system specifically designed for partial hand prosthetic patients."

And like other prosthetic developers, TouchBionics battles the three chronic



i-Limb Pulse/Touch Bionics

and seemingly intractable problems. “There is a constant goal in prosthetics to make the products lighter, smaller, and lower cost,” says Ford. “As the manufacturers of motors, controllers, and batteries continue to make strides in their development, Touch Bionics’ ability to utilize these new developments in prosthetics will continue to grow.”

Bringing a Bionic Limb to Life

The process of developing a new product begins with a review which converts inspiration into perspiration. “Our idea review involves a variety of measures including our capacity to deliver on the idea, the clinical implications of the idea, the market opportunity for the idea, and many other variables.” Once a “go” decision is made, prototypes are developed, reviewed for clinical, technical and fabrication merits and then sent out for field testing in real patients.

“The length of the field testing phase varies depending on the product and this is also the time that our marketing and

sales teams become intimately involved to clearly define how the product is performing and how the product will be explained to the market,” explains Ford. “The final, but critical piece of our product development process is an ongoing review of issues that may come up once the new technology is used more broadly in the field. This customer and patient feedback helps to drive not only improvements in the existing product but the development efforts on future product design.”

The i-LIMB Hand was the world’s first, multi-articulating prosthetic hand. It is a true bionic hand. Ford explains that what makes the i-LIMB so revolutionary is that it uses individual motors for each digit and allows the patient to control the hand with different grips. It’s also rechargeable and the battery carries a two-day charge.

Touch Bionics next generation i-LIMB will incorporate a pulsing grip technology that is controllable by the patient’s digits. “The new i-LIMB pulse features an aluminum chassis for enhanced durability, and a new software control system, known as BioSim, that allows the prosthetist to customize the function of the hand.” I-LIMB pulse will also offer increased grip strength as well as an audible and vibratory feedback loop to the patient. “The use of this technology allows an amputee to use more grip when they need to but only when they really want it.” Which means a patient can shake hands using the device or grip something which requires more pressure. The BioSim software is the key to the real-time feedback.

The Future at Hand

Ford says he sees many divergent fields merging to offer even more amazing bionics prosthetics. Cost is, however, everyone’s biggest hurdle. “There is little question that surgery, implants, neurology, and prosthetics are coming closer and closer. The major challenge, however, will be to find the most cost-effective combination of these capabilities. Prosthetics has long struggled to adequately explain the overall benefits that a patient receives from a successful, technologically advanced prosthetic fitting. As a result, insurance payers are hesitant to see the value to the patient of increasing costs of these technologies.

“The fields of orthopedics, prosthetics and neurology will need to work together to explain and document the true functional improvements that these advances can make to an amputee’s life. Once that communication step is taken, there is no question that the integration of prosthetics into the bionic equation will provide amazing life changes for amputees.”

One Patient’s Story

After cancer had weakened his immune system, Eric Jones suffered a severe case of strep pneumonia and sepsis which led to disseminated intravascular coagulation, a condition that cut off the blood supply to his extremities and threatened his life. Eric recovered but lost all digits on his right hand. Thankful to be alive, Jones says he took proactive measures to find a prosthetic. “I started looking on the Internet and stumbled upon Touch Bionics. I immediately thought that it was the newest and best technology available,



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ProDigits/Touch Bionics

and when I first met the prosthetists in Middletown, New York, I was right.”

But Jones’ expectations were realistic. “I expected to regain the ability to grip and grasp, and the bionic hand/fingers are excellent at doing that. When I visited the prosthetists to get the finished hand it was beyond awesome.” In fact, within five minutes he was operating the hand. “With practice, I can now

pick up individual potato chips and pop them in my mouth.”

One of the biggest issues a device such ProDigits solves is the need for opposing digits and come equipped with force sensing resistors (FSR or touch pad) and linear transducers, allowing patients to initiate movement even if they lack the muscle necessary for electromyographic signals.

Jones says he appreciates the ease with which ProDigits goes on and comes off as well as his new ability to grip and grasp. “The hand has a certain ‘wow’ factor that even to this day has not worn off. I enjoy showing how it works to people I might meet as I’m out and about during the day. It makes doing regular, everyday tasks so much easier, such as picking up a bottle of water, folding laundry, or taking items off the supermarket shelves. One of the best things I can do with the bionic hand is hold (and then eat!) a big juicy hamburger.” ♦

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The Future of Spine Is Here: SERC

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

NASS was aiming for the gold and they got it. The surgeons who created and are leading the charge to have the gold standard in orthopedic training facilities knew that to develop a center that would draw participants from around the globe, they needed to study what was...and create what was yet to come. From that mission, the North American Spine Society's Spine Education and Research Center (SERC) was born.

Eric Muehlbauer, the Executive Director of the North American Spine Society (NASS), was there at the beginning. "One day in 2004 I was talking with Dr. Jean-Jacques Abitbol, then President of NASS, about the state of spine training in the U.S. We knew that there were a number of facilities and that each had different, sometimes impressive, offerings, but that none that brought the best ideas all under one roof. Dr. Abitbol, who is quite a visionary, assumed the challenge of creating just such an institution."

Taking a cue from the business world, the thought leaders at NASS also took a deep breath...and went into debt. Muehlbauer notes, "NASS had never incurred debt before, but we went out on a limb and decided to follow the wisdom of a certain Harvard professor



SERC Surgical Lab/The NASS Spine Education and Research Center

who says that if a nonprofit organization is trying to facilitate its mission, then it is appropriate to embrace some debt."

With everything on the line, the leaders at NASS knew that they didn't want to waste time creating a second-class entity. "At the outset, several of us toured other bioskills labs around the country in order to gather the best ideas. As we moved through this process, we asked ourselves one basic

question, 'What is the optimal learning environment?' Time and again our answer was, 'Hands-on education.'"

What this came to mean in a concrete sense was that the organizers had to plan for the appropriate set of resources for each participant. "You shouldn't have too many doctors at any one bioskills station," says Muehlbauer. If it's an injection course then having four to six physicians is fine, but if

“As we moved through this process, we asked ourselves one basic question, ‘What is the optimal learning environment?’ Time and again our answer was, ‘Hands-on education.’”

it's a surgical course, then you want to limit it to two or three physicians. Through discussions with a number of people who had orchestrated hands-on courses we concluded that the maximum number of physicians you can train effectively at one time is about 40. Exceeding that number spreads your faculty too thin and makes it less likely that everyone will have a chance to get his or her questions answered.

Charles Branch Jr., M.D., former President of NASS, has been part of the growth of SERC. He notes, "I have never seen a facility quite as impressive as SERC. There are more than 100 seats in the tiered auditorium, with computer jacks and microphones for participants. When you speak into the microphone there is a video camera on the front wall that zooms in on you to produce the effect of a videoconference...and you can stream content anywhere in the world. For example, surgeons in Australia could watch a live training course along with the participants at SERC. The courses also can be viewed later online with a designated password."

Dr. Branch adds, "Over the last several years SERC has become a highly utilized education and training facility. It is unique in that it crosses the multidisciplinary boundaries that NASS has embraced as a society. Along with surgical courses, we have physical therapy training, exercise courses, coding and reimbursement, etc. And it is pretty impressive that anyone who participates in these courses can walk

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SERC Auditorium/ The NASS Spine Education and Research Center

“ There are more than 100 seats in the tiered auditorium, with computer jacks and microphones for participants. When you speak into the microphone there is a video camera on the front wall that zooms in on you to produce the effect of a videoconference...and you can stream content anywhere in the world. ”

out of the door at the end of the day with a DVD of the course in hand.”

“The SERC facility also is utilized by medical device companies and other medical societies who want to conduct didactic and hands-on training,” says Eric Muehlbauer. “We have a well-trained lab staff and a significant amount of instrumentation that organizations may use, as well as 8 C-arms and an O-arm. Additionally, our highly skilled audiovisual technicians are available to assist with presentations in the auditorium and recording in the lab.”

As former participants have gone on to spread the word about SERC, the phone, says Muehlbauer, is ringing. “I

have received inquiries from several organizations that are interested in replicating our processes and resources. Recently, the EuroSpine Foundation leadership visited the facility and had detailed discussions about what they would like to accomplish. Also, we just held a spine summit with 11 other medical societies. To any of these groups seeking to emulate our process or facility, I say, ‘Walk before you run. Attend a course at our facility to gather information on how we manage things.’”

Sometimes other organizations use SERC...and sometimes SERC staff “takes the show on the road.” Eric Muehlbauer: “I see this as a slow, but steady growth area for us as we augment our resources

in the years to come. Our major push now is to expand the number of courses that we hold during the week (as most of them are currently held Friday to Sunday). This is growing, with several companies renting the facility for smaller courses, and bench testing of new instruments and devices as well as using it for calibration of diagnostic equipment and sales training. The bottom line is that SERC has a very high customer satisfaction rating. Once an organization or company utilizes SERC they usually come back because of the facility and the great customer service.”

Ray Baker, M.D., President of NASS, takes a broad part in the workings of the facility. He states, “I view my role at



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“ I would like to see us host more webinars and distance learning programs where the equipment and expertise can be centered at SERC, but learners interact through online discussions and by viewing content over the Internet. ”

SERC as primarily one of strategic planning. In general, the executive committee at NASS is now more involved in oversight and strategic planning and less involved in day-to-day operations. In five years, I would like to see SERC extend beyond what has been viewed as traditional CME events (cadaver courses and meetings). I would like to see us host more webinars and distance learning programs where

the equipment and expertise can be centered at SERC, but learners interact through online discussions and by viewing content over the Internet. I also want to strongly push podcasts and other online content that can be an economic engine for NASS. The content can allow U.S. providers to obtain CME credits without traveling to SERC, and can also be a terrific way to allow international providers to be exposed to the latest treatments and techniques.

So as not to get off-track in spine, says Dr. Baker, NASS needs to get hip. “We must remain in step with our younger members, who are the future leaders in spine care. The Internet is much more important nowadays in social networking and in learning overall. NASS is committed to evolving with the needs of our members, and we are using Facebook, Twitter, blogs and other social networks to allow members to interact. We also are offering more Internet-based learning. All of this leverages the IT infrastructure, the equipment, and the expertise centered around SERC.”

The future—even busier than the present—demands the very qualities offered by the Spine Education and Research Center—flexibility and up-to-the-minute, credible information. Find this and more at SERC. ♦

Some of the features at the Spine Education & Research Center:

- Auditorium with tiered-seating to accommodate 100+ guests
- 3,800 sq. ft. bio-skills lab with 12 fully-equipped work stations
- Movable beds at each station
- 14 ceiling-mounted LCD displays to view lead faculty procedures
- Cutting-edge multimedia center including HD camera mounted in overhead light for main station
- Didactic and lab recording capabilities
- Certified CSTs and RTs
- An O-arm for 3-D imaging and 8 C-arms
- Sterilizer and instrument washer
- 150 sq. ft. secured specimen storage

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Stryker Buys Gaymar for \$150 Million

It's confirmed. Stryker bought it.

No, not Boston Scientific's pain management business, but the ulcer management business owned by privately held Gaymar Industries.

Stryker announced on August 25 that the company had reached a definitive agreement to acquire Gaymar Industries for approximately \$150 million in an all-cash transaction.

Support and Pressure Ulcer Management

Gaymar, founded in 1956, specializes in support surface and pressure ulcer management solutions as well as targeting the temperature management segment of the healthcare industry, with a portfolio of capital and disposable products in both the U.S. and international markets. The transaction is expected to close by October 1, 2010.

\$1.8 Billion Market

Stryker CPCEO Stephen MacMillan said the acquisition was consistent with Stryker's strategic goals of "expanding our existing product offering and extensive sales force presence via innovation and value added products." He added that Gaymar's portfolio of high-performance support surface and pressure ulcer management products target an approximately \$1.8 billion worldwide market and the temperature management products enhance Stryker's existing customer relationships.

Gaymar's CEO Kent Davies said the integration of the portfolios will, "strengthen Stryker's leadership in patient handling while driving innovations that can help prevent adverse events and reduce healthcare costs."

10-Year Relationship

Stryker's Medical division and Gaymar have had a 10-year original equipment manufacturer (OEM) relationship whereby Gaymar has been providing Stryker with exclusive rights to sell support surface and pressure ulcer management products to acute care customers in North America.



Therapeutic Mattress/Gaymar Industries

The announcement by Stryker included a discussion of Gaymar's refocused business strategy following the global economic contraction in late 2008 and early 2009. According to the statement, Gaymar "has since demonstrated an impressive recovery consistent with its history as a growing specialty products company. Gaymar achieved sales of approximately \$77 million in 2009, of which approximately \$14 million were related to the existing OEM relationship with Stryker."

The \$150 million deal will barely dent Stryker's \$4 billion war chest in available cash for mergers and acquisitions.

—WE (August 25, 2010) ♦

legal

DePuy Warned Over TruMatch and Corail

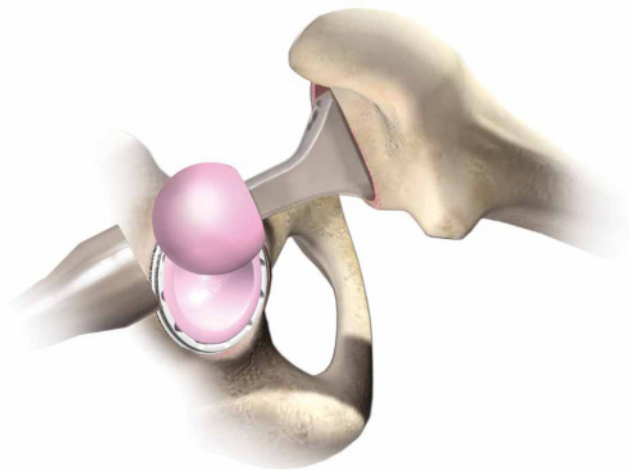
DePuy Orthopaedics is the second device company to receive a warning letter from the FDA recently regarding a personalized patient care system.

Biomet got one on July 27. DePuy's came on August 19. Is Stryker's OtisMed next?

The FDA says the companies have not obtained marketing approval or clearance for the systems. The systems, Biomet's Signature and DePuy's TruMatch, generate a computerized roadmap of a patient's anatomy that is then used by a surgeon to navigate proper placement for a knee replacement.

Corail Hip "Unapproved" Uses

DePuy got a two-fer however. Their warning letter also included a demand to stop marketing the Corail Hip System for "unapproved" uses.



Corail Hip System/DePuy Orthopaedics

The FDA granted clearance for the Corail in 2009 for total hip arthroplasty "in patients where there is evidence of sufficient sound bone to seat and support the components." In addition, total hip replacement was indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The nonporous Corail is indicated for cementless use only.

However, the FDA says a brochure on DePuy's Web site promotes the use of the Corail for osseointegration, "a major change or modification in the intended use of your device that require a new premarket notification."

The FDA gave DePuy 15 days to let them know of the specific steps the company has taken to correct the (alleged) violations, including an explanation of how the company plans to prevent these violations from occurring again.

DePuy issued a statement saying the company was "reviewing the letter to understand the FDA's concerns and will respond to their request for information."

No safety issues were cited in either letter to DePuy or Biomet.

You can read the warning letter here: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm223613.htm>

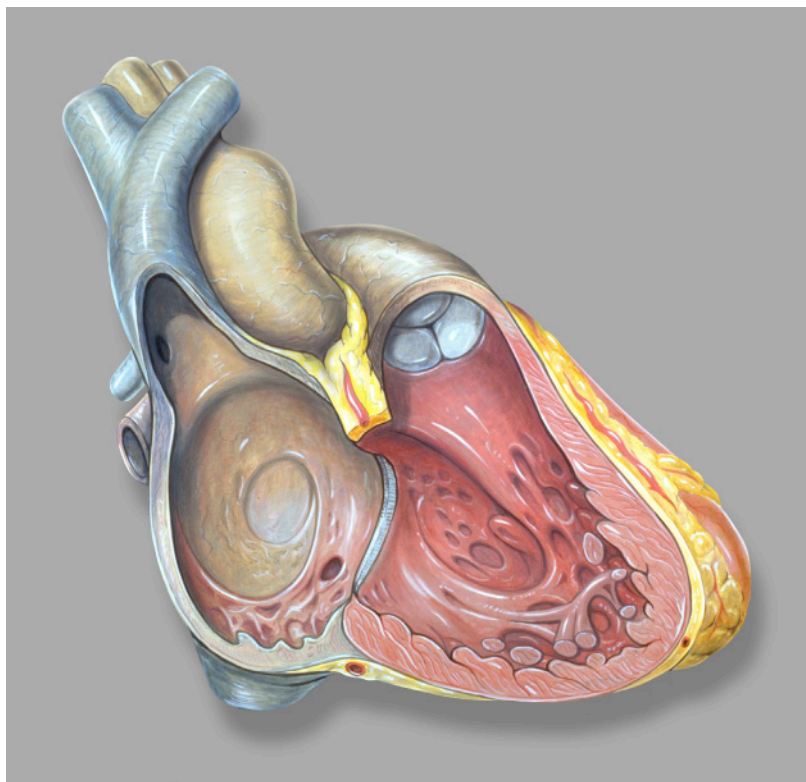
—WE (August 24, 2010) ♦

large joints

Perioperative Ortho Care and Cardiac Outcomes

A new study has found that the quality of immediate postoperative care of orthopedic surgery patients has important effects on patients' long-term cardiac outcomes. According to lead study author Sylvain Ausset, M.D., from Percy Military Hospital in Clamart, France: "Looking at long-term outcome, especially for mortality, is currently the gold standard for postoperative care, but it is difficult to obtain this end-point, and obviously needs a fair amount of time to occur," said Dr. Ausset in the news release. "What we sought was an indicator that would be quickly and easily available."

Over three years, the researchers measured troponin levels on the first three days after surgery in 378 orthopedic surgical patients to determine if there was any correlation between raised troponin levels and long-term cardiac outcomes. Troponin is a



Heart, Patrick J. Lynch, medical illustrator; C. Carl Jaffe, MD, cardiologist, Creative Commons

protein measured to determine whether physiologic stress related to surgery has caused heart damage.

Dr. Ausset's team then modified postoperative care to reduce the occurrence of events that were thought to lead to increased episodes of myocardial ischemia based on raised troponin levels. Reducing the incidence of myocardial ischemia was found to be important in lowering the incidence of cardiac problems (even years later).

In a companion editorial on the study, Don Poldermans, M.D., Ph.D., of Erasmus Medical Center, Rotterdam, Netherlands, indicated that the results of Dr. Ausset's study could help to improve quality of care in orthopedic surgical patients by providing firm evidence for the development of clinical practice guidelines.

As for why they selected orthopedic surgery, Dr. Ausset told *OTW*, "For years the issue of perioperative myocardial ischemia has been mainly explored in vascular surgery since, due to a high incidence of both risk factors and complications, it was easy have many events with a few patients to enroll. As a result, most of our knowledge is derived from extensive experimentation on a small subgroup of patients (in France, only 2.5% of surgery is vascular surgery). Alternatively, we have chosen to address this issue in the orthopedic surgery setting because, even if the incidence of such a complication was lower, due to the number of patients involved (orthopedic procedures represent one fourth of surgery in France) the public health burden could be greater. Also, the major orthopedic surgery aggregates a lot of risk factors associated with aging and in the future

this kind of population is expected to increase steadily."

He also commented to *OTW*, "The actual risk associated with surgical procedures cannot be accurately measured with in-hospital data, especially when the length of stay is short. Also, our study confirms the impact on the long-term outcome of in-hospital complications—even asymptomatic—previously shown by several studies (Halm *EA Arch int medicine* 2003, Manku *K Anesth Analg* 2003, Shukri *Ann Surg* 2005)."

—EH (August 27, 2010) ♦

Gender Knee Study Draws Attention

The Korean surgeons were surprised. Robert Booth, M.D., the father of the gender knee was amused.

The Koreans conducted a study which concluded that 85 women who received a Zimmer's gender-specific NexGen LPS-Flex knees had no clinical benefits when compared to the company's standard knees. The study was published in the *Journal of Bone and Joint Surgery*. The lead author was Young-Hoo Kim, M.D., of The Joint Replacement Center of Korea, Ewha Women's University School of Medicine in South Korea.

Study Results

The women were assessed for at least two years after surgery. The two knees had similar knee scores and similar range of motion while lying down (125° for the knees with standard implants and 126° for the knees with gender-specific implants). All patients

except three were able to bend their knees at least 90°.

Additionally, patient satisfaction with the implants was similar (8.3 points for the standard implants and 8.1 points for the gender-specific implants). A rating of 6 to 8 meant “satisfied,” and a rating of 9 to 10 meant “fully satisfied.”

Kim and his colleagues were surprised by the study results. “We indeed expected the gender-specific prostheses to outperform the standard prostheses,” he said. “Our data demonstrated that the standard prosthesis fit the distal part of the femur (where the thigh and knee connect) better than the gender-specific prosthesis did,”

Booth Amused

Robert E. Booth, Jr., M.D., was also surprised...and amused. Although for different reasons.

Booth told OTW, “What is amazing about this study is that the gender femur did not actually produce worse results than the standard, as it was not designed for this population of women whose femoral aspect ratio is the opposite of Caucasian women. Indeed, there are currently available Asian femurs to address this morphologic subset, and they would be the proper subject of a similar analysis. This clearly explains the increased amount of exposed bone and bleeding reported.

“The indiscriminate use of any device is unlikely to produce its intended result.

“What is amusing about this study is that the over-exuberant—and hugely successful—direct-to-consumer marketing of the gender femur concept has generated enormous animus in the orthopedic

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community. Further, every current critic of the gender knee uses—to my knowledge—handed femoral components, for which there is no more literary justification than gender. Shape and size are different issues, and only an unbiased appreciation of their separate impacts on knee design will advance our art.”

Zimmer Encouraged

Zimmer was encouraged that studies are continuing to understand the differences among various patient populations.

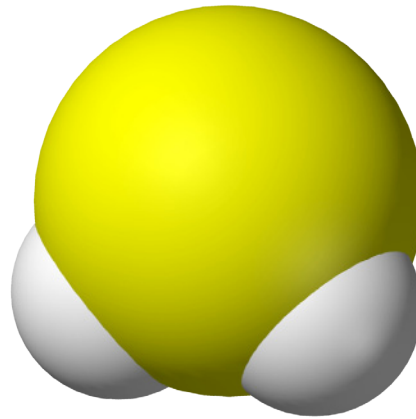
A company spokesperson told OTW, “There is a preponderance of clinical evidence and publications that support the need for this technology, including a dynamic study recently published in the *Journal of Bone and Joint Surgery* titled “Overhang of the femoral component in total knee arthroplasty: risk factors and clinical consequences.” The study highlights the prevalence of ≥ 3 mm of overhang in females being up to 68% in at least one zone with a particular knee system.

The study also determined that this 3mm of overhang was associated with a twofold increase of knee pain more severe than occasional or mild at two years after surgery. The company looks forward to additional studies supporting the need for Gender Solutions technology reaching publications later this year.”

—WE (August 26, 2010) ♦

Rotten Eggs and Rotten Knees

You can run from the rotten egg smell—hydrogen sulfide (H_2S)—but you can't run from your knees...



Hydrogen Sulfide - Ben Mills/Wikimedia Commons

but that may be OK. H_2S has now been found to naturally reside in knee joint synovial fluid. The UK researchers who made this discovery—from the Peninsula Medical School and the Royal Devon & Exeter NHS Trust in Exeter—indicate that synovial fluid H_2S may help reduce joint inflammation.

The study compared H_2S in blood samples and knee-joint synovial fluid from patients with rheumatoid arthritis (RA), osteoarthritis and healthy individuals. RA patients had higher concentrations of H_2S in their synovial fluid compared to controls and up to four-fold higher levels than in blood samples from the same patients.

Study leader Dr. Matt Whiteman told OTW:

“We have been working on various aspects of inflammation for several years. In particular, how the different types of cells involved in the inflammatory response communicate and interact with the surrounding tissue. We have previously showed that levels of H_2S are increased in acute and chronic inflammation (in animal models) but didn't

really know whether that was a good thing or a bad thing. Previously used approaches have added simple sulfide salts (e.g. Na_2S or $NaSH$) to cells or animals to get a response and these have tended to show that H_2S was bad. However, these compounds release H_2S extremely quickly as one concentrated bolus but the enzymes in the body that make H_2S do so very slowly over a long period of time.

When we've added compounds that we've made to release H_2S in a more physiological manner, they show marked anti-inflammatory activity (tested so far in endotoxic shock and cell culture systems). So together with the increased H_2S in the synovial fluid from patients with rheumatoid arthritis that we report the paper below and the fact that H_2S levels correlated with a lower count of inflammatory cells, we now think H_2S is increased as the body's own natural anti-inflammatory defence mechanism. This is also supported by the fact that in endotoxic shock or isolated macrophages slow release of H_2S switches off pro-inflammatory cytokine synthesis but increases the synthesis of the body's own anti-inflammatory molecule IL-10.”

Dr. Whiteman also commented to OTW, “We have just won Wellcome Trust (UK) funding to continue this work using synoviocytes to examine precisely how H_2S is synthesised in the joint and work out the mechanisms for its anti-inflammatory effects. Similarly, in collaboration with other researchers in Exeter, we are working on and developing novel slow releasing H_2S

donor compounds to investigate the therapeutic potential of H₂S in treating inflammatory conditions, including arthritis.”

—EH (August 24, 2010) ♦

Zimmer's Periprosthetic Solution

Zimmer has completed the first implantation of the company's NCB (Non-Contact Bridging) Periprosthetic Plating System.



NCB Periprosthetic Plating System/Zimmer Holdings

Hip and knee replacements are extremely effective procedures. However, they can be complicated by periprosthetic fractures. Zimmer says they've come up with a solution.

Zimmer Claims a First

The company announcement on August 12 stated that the system is the first comprehensive solution for addressing

the complex femoral fractures which can occur around the hip or knee. The company says its system is the first set of plates and screws that specifically addresses the issues of difficult fixation and poor bone quality surgeons face when addressing periprosthetic fractures.

Wider Plate Equals More Stability

The system features a wider plate design in the region near a patient's hip or knee implant. This feature, according to the company, allows for stable fixation around the prosthesis, while a narrow design along the rest of the plate minimizes soft tissue disruption. The company says the stability is achieved from a combination of plate design, polyaxial screw placement, and a fixed angle construct. Bicortical screws can be placed within a 30° polyaxial cone and secured at any time intraoperatively using locking caps. This locking construct provides angular stability which can be advantageous when working around a prosthesis or in osteopenic bone.

For cases where bicortical screw fixation cannot be achieved due to poor bone stock or other factors, the system is fully compatible with the cables and cable buttons of the Zimmer Cable-Ready System. For added flexibility, locking screws and cables may be combined in one construct. Blunt tip unicortical NCB Screws are also available.

Curt Jennewine, Vice President, Marketing Zimmer Trauma, said, "With the demand for joint replacement rising, it has become increasingly important to provide surgeons with an effective and reliable solution for the

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potentially difficult fractures which can occur around a hip or knee prosthesis.”

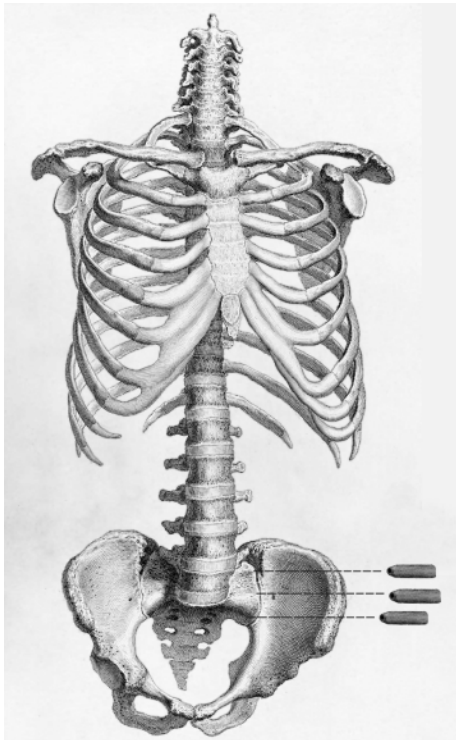
Julie Johnson, the brand manager in charge of the system told *Medical Device Daily*, “When a surgeon goes in to do the surgery they may not always appreciate the true complexity of the fracture and they may want to use a different plate than they had planned for,” She said that having a comprehensive solution available, the surgeon would already have the device in the operating room and would not have to send someone out to find it.”

The system received FDA 510(k) clearance in June and is scheduled for full release this fall.

—WE (August 24, 2010) ♦

SI-BONE Closes on \$11 Million

Sacroiliac (SI)-BONE, Inc., manufacturer of the iFuse Implant System, has announced that it has closed \$11.0 million in financing, with the round being led by new investor Skyline Ventures of Palo Alto, California. The goals of the financing are:



Manipulation of a William Cheselden drawing, RRY Publications

- To increase worldwide sales and marketing operations
- To expand the company's clinical efforts through a retrospective minimally invasive surgical (MIS) SI joint treatment study, a prospective, multicenter study (MISSION- Multicenter, Open Label, Prospective Study to evaluate clinical and economic efficacy of iFuse), a European prospective study, additional post-market case studies and an animal

study validating arthrodesis with the iFuse implant to further establish clinical efficacy

- To educate spine surgeons and referring specialists in the U.S. and Europe

Glenn Reicin, a partner at Skyline Ventures, will join the SI-BONE Board of Directors, said in the news release, "One of the reasons we invested in SI-BONE is our belief that the number of patients who suffer from SI joint dysfunction is large and dramatically underserved. Further, we believe that the minimally invasive technology and procedure invented by Dr. Mark Reiley has huge potential based on early patient results that the surgeons currently using the procedure are seeing. We are very confident in the management team led by Jeff Dunn, President and CEO. We look forward to helping them accomplish their mission of helping many patients worldwide."

The iFuse Implant System is commercially available in the U.S. for fracture fixation of large bones and large bone fragments of the pelvis for conditions including sacroiliac joint disruptions. The system involves a minimal incision for delivery and implantation of small, titanium implants coated with a porous plasma spray that acts as an interference surface, designed to help decrease implant motion. These implants have substantial thickness and sophisticated metallurgy and are able to produce a much stronger construct than that of conventional pins or screws used to surgically fix bony structures.

CEO Jeff Dunn told *OTW*, "The financing will further help position iFuse as the frontline MIS therapy for patients with SI joint syndromes who are unresponsive to conservative

therapy. As for the surgeon education, we will significantly ramp up the training classes (didactic and hands on) for spine surgeons, as well as the referring physician programs. We will also have an expanded presence at key spine and low back meetings, with targeted symposia and presentations."

Glenn Reicin commented to *OTW*, "The number of patients who suffer from SI joint dysfunction is large and dramatically underserved...and we believe that the minimally invasive technology and procedure invented by Dr. Mark Reiley has huge potential based on early patient results."

—EH (August 23, 2010) ♦

spine

New Arrival to Aesculap Implant Brood?

Aesculap Implant Systems recently received FDA 510(k) clearance for its A-Fix Spinal System. Which means you want to know more about Aesculap.

So the big FDA 510(k) clearance news from Aesculap Implant Systems goes as follows: clearance under K100802 for the A-Fix Spinal System. A-Fix is a stand-alone "interbody fusion device" according to Kevin Gilmore, Group Product Director for Spine for Aesculap Implant Systems. The system is a stand-alone interbody fusion device that Aesculap has developed for the anterior surgical approach to spinal surgery and was designed for spinal fusion procedures at one or two contiguous levels in the lumbar spine. It's applicable for locations from L2 to S1 specifically for "patients with degenerative disc disease with up



Morguefile

to Grade 1 spondylolisthesis at the involved level(s).”

Aesculap Implant Systems is a subsidiary of Aesculap, Inc. the U.S.-based unit of Aesculap AG, a surgical instruments supplier. Aesculap AG in turn is a part of the larger B. Braun Melsungen, the German medical device manufacturer.

For its part, Aesculap has a diverse line of products in itself, which includes neurosurgical, cardiac, orthopedic, laparoscopic and thoracic surgical supplies, along with electro-surgical devices and power systems. The subsidiary also offers consulting and training, as well as supply chain management services.

The history of Aesculap actually dates back to 1867 Germany. Over the years the company has kept its focus on surgical instrument development and supply. But due to a growing customer base in spine and orthopedics, Aesculap Implant Systems was created and currently features a full line of

products for this market, including knee and hip arthroscopy, power tools, navigation equipment, and sports medicine devices.

Within the spine market, Aesculap Implant Systems develops and manufactures biologics such as ProSpace DBM-D scaffolding, distraction devices, anterior cervical and thoracolumbar products as well as high speed drills and a host of other interbody fusion devices.

—JR (August 27, 2010) ♦

biologics

Orphan Drug OK for BioMimetic

Having any disease is problematic... But having a rare one brings special challenges. Now, thanks to the efforts of those at BioMimetic Therapeutics, patients suffering from osteochondritis dissecans (OCD) of

the knee, elbow or ankle, have hope. BioMimetic has announced that it has received orphan drug designation from the FDA for its protein therapeutic, recombinant human platelet derived growth factor (rhPDGF-BB), to be used in conjunction with autograft and/or commercially available osteochondral allograft for the treatment of this rare joint condition.

“We are fortunate that our rhPDGF-BB platform technology has the opportunity to improve healing across a broad array of injuries. In sports medicine, we’ve had a robust product development program for some time evaluating product candidates for tendon, ligament and cartilage repair. This orphan designation should facilitate this work in the cartilage area,” said Dr. Samuel Lynch, president and CEO of BioMimetic Therapeutics, in the news release.

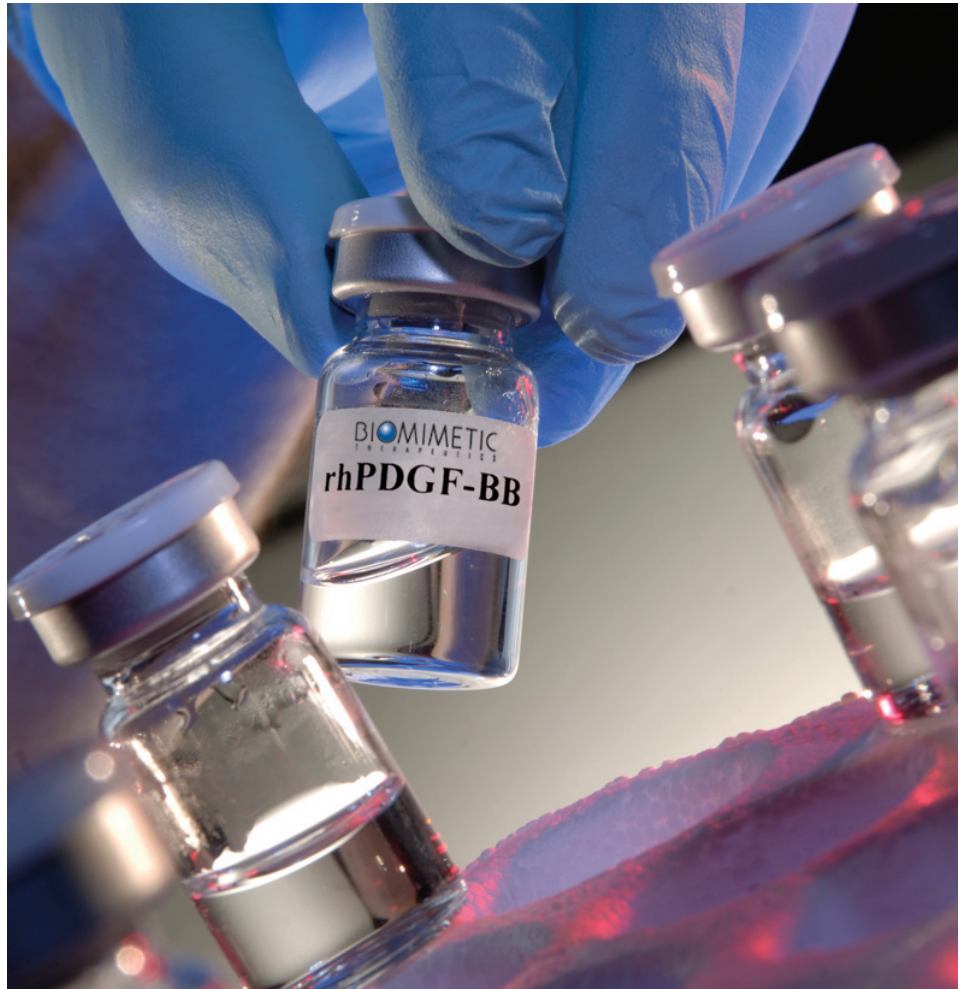
Hans Kestler, VP of Sports Medicine told OTW, “We recognized that several epidemiological studies indicated a low prevalence of OCD, and that it could qualify as a rare, or orphan, disease. Furthermore, the etiology of OCD includes a lack of blood supply that results in a bone and cartilage defect. Based on the well characterized mechanism of action of rhPDGF-BB, which has been shown to have positive effects on both angiogenesis (blood vessel formation) and the cell types needed to regenerate bone and cartilage, namely osteoblasts and chondrocytes, we hypothesize that the application of rhPDGF-BB could improve healing in this difficult-to-treat patient population.”

He added, “We recently released pre-clinical data on several sports medicine indications, not including

OCD, and have said that we plan to initiate a sports medicine pilot clinical trial around year end. That guidance has not changed, and an OCD study, if approved, would be in addition to another sports medicine trial.”

Russ Pagano, VP of Clinical and Regulatory Affairs for BioMimetic, told *OTW*, “This designation is related to the sports medicine area (soft tissue/cartilage) as opposed to bone. The orphan drug designation is not an approval to start a study, rather it is a designation allowing us to follow up with an IND (Investigational New Drug) application. The IND application must contain information in three broad areas, including animal pharmacology and toxicology studies, manufacturing information and clinical protocols and investigator information. Once submitted, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk. We plan to file the IND for OCD sometime next year.”

—EH (August 25, 2010) ♦



BioMimetic Therapeutics, Inc.

THE PICTURE OF SUCCESS

Jeffrey N. Katz, M.D., MSc

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



“Success” has many definitions. For Dr. Jeffrey Katz, who has a CV that would define success in any context (Director of the Orthopaedics and Arthritis Center for Outcomes Research at Brigham and Women’s Hospital, Professor of Medicine and Orthopaedic Surgery at Harvard Medical School and the author of several seminal research studies) and who is one of the Masters of his profession, “success” has come to mean something deceptively simple and powerful. For Dr. Katz, success emanates from that most honorable position of having a “front row seat in patients’ lives.”

One of the great gifts of writing *Orthopedics This Week’s* Picture of Success is to meet people like Dr. Katz, for whom the meaning of their stellar careers has become the same meaning that brought them into the profession: a sense of giving and a mission to heal. For us, as observers, we often find that the most credentialed people we interview talk about the most simple, enduring and true aspects of their profession. So it is with Dr. Katz.

How did Dr. Katz develop this rare combination of skill, discipline and compassion? Born and raised in Connecticut, Jeffrey Katz and his two siblings were under the care of parents who held them to exacting standards. “My mom was a teacher and my dad was a pharmaceutical sales rep; they both imparted an extraordinary work ethic to us kids. I studied hard, but it wasn’t until college at Princeton that I even considered medicine. Because I excelled in math and science I initially enrolled in the engineering program; I soon realized, however, that working with people would afford me the chance to get involved in fascinating dilemmas. I also liked the idea of going to work every day, having a front row seat to human struggles, and helping people find solutions.”

But solutions to problems are never as obvious as they might initially appear, as Jeffrey Katz learned when he entered the intellectual hotbed of Yale Medical School in 1984. However, he learned that wandering into uncharted territory, if done with purpose and an

analytical mindset, can be productive. “I was fortunate to have been trained in critical thinking and analysis at Princeton. It’s interesting that nearly everything I learned in the 1970s has been supplanted—everything except for how to take a critical approach to thinking and writing. Today I teach students that these are the most important skills they can develop.”

A cool-headed thinker, Dr. Katz did find himself heating up when it came to certain less-than-professional behavior he encountered in his early years of training. “It was the 1980s and there was still some overt sexist and racist language being used during rounds. I learned that these early training years are a time during which budding doctors must ask themselves, ‘How much of what I hear do I want to internalize?’ When I began to move into positions of authority I set expectations about what kinds of discussions regarding patients were unacceptable. I told my trainees, ‘Their backgrounds and what brought them here are not ours to judge.’”

“ I also liked the idea of going to work every day, having a front row seat to human struggles, and helping people find solutions. ”

Interested in the fundamentals of orthopedics, but of the opinion that he wasn't "much good" with his hands, Dr. Katz pursued an internal medicine residency at Yale-New Haven Hospital, followed by a rheumatology fellowship at Brigham and Women's Hospital. It was during this time that he fully understood that curiosity, rather than judgment, leads to compassion. "I worked with patients who were in the hospital for self destructive reasons, such as smoking or drinking. I have always tended to view self destructive behavior as a symptom of a difficult social circumstance or as part of the person's primary disorder. The fundamental thing is to meet the patients where they are. It is only then that we can help them move forward."

Often, meeting a patient where *they* are means temporarily leaving behind where *you* are. Dr. Katz: "Sometimes patients want to have a test done that you think is unnecessary. Because as physicians we have a responsibility to spend resources wisely, there is an inherent conflict because we are also supposed to be the patient's advocate. I talk with patients and try to understand where their impulse to have the test is coming from. I've often found that regardless of the MRI results, patients can be as unhappy as they were *before* the test. Typically, patients will not engage in a technical argument with a doctor; instead, they just feel that more should be done because they are suffering. Underlying this is often a feeling that the doctor may not really care."

One way of building trust, be it with an easygoing or more challenging patient, is to build bridges. "I teach residents that a great way to lower a patient's guard is to identify an area of shared interest. I ask about patients' favorite baseball team, the books they enjoy, etc. Going 'off agenda' helps to humanize the interaction and makes it safe for patients to open up...and easier for you to help them."

Dr. Katz is also one of the most prolific research scientists in the United States, having been awarded funding from the National Institutes for Health (NIH) and other entities on multiple occasions.

"I am the Principal Investigator (PI) on the Meniscal Tear in Osteoarthritis Research Trial, an NIH funded, seven center randomized controlled trial of arthroscopic meniscectomy versus nonoperative therapy in patients with symptomatic meniscal tear and concomitant osteoarthritis. While there have been several trials of arthroscopy and osteoarthritis, none of these examined meniscal tears. At this point we have nearly 75% of patients enrolled, with our target being 340 participants. The challenge is to keep the entire team—about 75 people around the U.S.—stimulated and engaged."

"I am also the PI on a project regarding the failure of total hip replacement. At present we have hip replacement data from 29 states going back to 1995. We are now determining what the predictors of revision were, and should have definitive answers next year."

And to benefit future clinician-researchers, Dr. Katz is making strides via COMET, the Clinical Orthopedic and Musculoskeletal Educational and Training Program. "I am the PI and Program Director for COMET, an NIH funded pre and postdoctoral training program for clinical research in musculoskeletal disorders. While NIH has funded numerous research training programs, not many of them are clinical in nature."

In 2007 Dr. Katz received the Clifford Barger Award for Excellence in Mentoring from Harvard Medical School. "I'm very proud of that award as I take the mentoring relationship seriously. I caution future mentors that it is easy to take talented people and guide them in furthering your own research interests. It is harder to help people grow into their own potential when it doesn't further your particular research interests."

As the Deputy Editor for Methodology for the *Journal of Bone and Joint Surgery*, Dr. Katz is influencing the quality of research and treatment for generations to come. "Many people aren't trained in methodology; I see my job as applying high methodological standards so as to sharpen the quality of research. As we elevate the standard of these journals, researchers will hopefully realize that they should think more carefully about design and methodology during the early stages of their work. We sometimes find problems that can't be fixed at the writing stage and so we must reject the

“ I have always tended to view self destructive behavior as a symptom of a difficult social circumstance or as part of the person's primary disorder. The fundamental thing is to meet the patients where they are. It is only then that we can help them move forward. ”

“The fact that researchers are still doing studies with no controls or doing case series (which is not methodologically rigorous), is proof of the need for more formalized research training.”

submission. The fact that researchers are still doing studies with no controls or doing case series (which is not methodologically rigorous), is proof of the need for more formalized research training.”

Of his particular specialty—arthritis—Dr. Katz notes, “Regarding osteoarthritis (OA), the most common form of arthritis, to date there is no structure modifying drug. Fortunately, the surgical management of OA is very successful. Going forward, we should focus on catalyzing drug development, as well as on establishing a plan to determine which of our treatments are actually successful.”

While data often need a fresh set of eyes, at times, so does one’s perspective on medicine. Each spring Dr. Katz is afforded a renewed appreciation for patient care. “I do volunteer work in the Dominican Republic with Operation Walk Boston, a wonderful medical service organization. It is so inspiring to witness the resilience of the Dominican patients, their appreciation for our work, and the speed with which they rehabilitate. It is heartening the way patients there seem more ready to trust the doctors; they are very willing to share the private aspects of their lives.”

When he steps off a plane or locks up the lab for the night, Dr. Katz returns to a place of repose. “I have a delightful wife and two

sons, one 18 and one who is 14 years old. When not ‘hanging out’ with my family, I clear my head by biking around our neighborhood in Massachusetts, and keep up with the latest reading ‘assignments’ of my book club.”

As for the future of the medical world, says Dr. Katz, physicians should rely on some fundamentals. “Medicine changes so rapidly that it is difficult to keep up with all of the advances. Patients are good teachers... we doctors have to be good students. It’s all about figuring out how to help them handle their suffering.”

Dr. Jeffrey Katz...who has built his exemplary career around the true definition of success—namely, that it is all about what you do when you are in that most honorable position of being at the “front row seat in patients’ lives.” ♦

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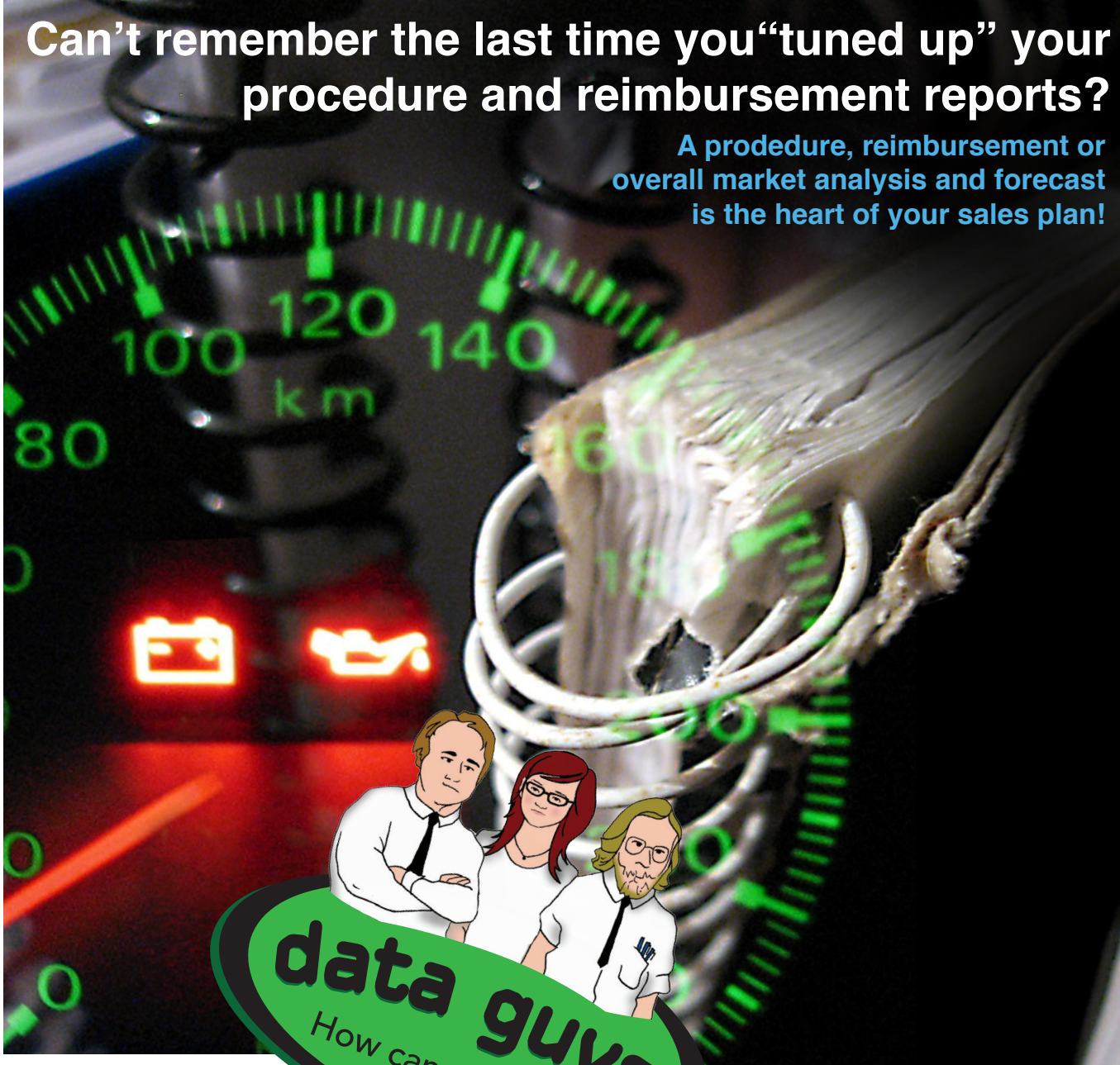
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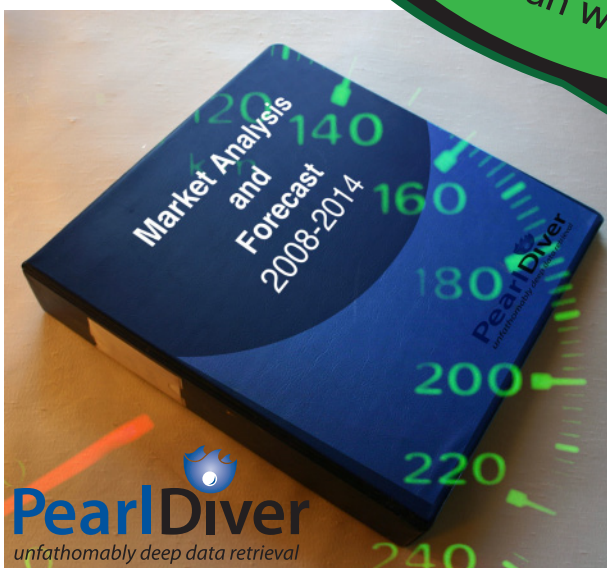
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