Spine Company Count Tops 100; Segment Still on Fire

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In 2007, spine revenues in the U.S. exceeded $4.1 billion, an increase of 13 percent over 2006. The ten largest companies – Medtronic, DePuy Spine, Synthes, Stryker, Zimmer, NuVasive, Globus, Orthofix, Biomet and Abbott Spine – accounted for 91 percent of U.S. spine revenues in 2007. With these ten companies controlling the lion's share of the U.S. spine market, you might think that others would view the market as perhaps too difficult to penetrate. Well, that's simply not the case. In fact, at least 50 companies have entered the market with FDA-cleared products since we introduced *U.S. Orthopaedic Product News* (OPN) in 2005. All told, more than 100 companies are either developing or marketing spine products for the U.S. spine surgeon and the influx of newcomers does not appear to be waning.

With this kind of intense competition, a lot can happen in the span of a year. And it did for the last 12 months. In this article, we'll review what's happened in the U.S. spine space since our last update in September of 2007.

A number of clinical firsts occurred over the year – including some ex-U.S. happenings:

- 1st patient treated in a pilot study of TranS1's Percutaneous Nucleus Replacement (PNR) implant (in the Netherlands)
- 1st implantation of VertiFlex's Superion Interspinous Spacer in a U.S. clinical trial
- 1st human implantation of the True Total Spinal Motion Segment System (artificial lumbar disc + posterior dynamic stabilization device) from Disc Motion Technologies
- 1st human implantation of the NuNec Cervical Arthroplasty Device from Pioneer Surgical Technology
- 1st human implantation of the Archus Orthopedics TFAS-C system for treatment of spinal stenosis (in Europe)
- 1st patient enrolled and implanted in Spinal Kinetics' U.S. Feasibility Study patient of the M6-C cervical disc
- 1st implantation of the Zyre Facet Implant System from Spinal Elements
- 1st patient surgery with the OsseoFix (formerly V-Stent) from Alphatec Spine
- 1st implantation in Globus' IDE for the FLEXUS interspinous spacer
- 1st surgery in the U.S. using a less-invasive version of Impliant's TOPS Total Posterior Arthroplasty device, which is in IDE
- 1st surgery using Theken Spine's FDA-cleared Vu aPOD anterior lumbar intervertebral fusion implant

In FDA clearances and clinical trials…

Synthes joined Medtronic in offering a cervical disc to the U.S. spine surgeon. FDA cleared the company's ProDisc-C Total Disc Replacement in late 2007. Controlled rollout of the product began in early 2008 and continues in a typically Synthes manner – conservatively and with very little fanfare. Synthes remains the only company in the U.S. with clearance for both lumbar and cervical disc replacement products.

In other motion preservation news since the spine update in OPN last fall, Orthofix entered clinical trials for the Advent cervical disc and Applied Spine announced enrollment of the 100th patient in its randomized, controlled study comparing its Stabilimax NZ Dynamic Spine Stabilization System to traditional fusion in the treatment of lumbar spinal stenosis. Facet Solutions completed one-year follow-up on the first cohort of patients to receive its Anatomic Facet Replacement System and more than 180 patients have been enrolled in a prospective, controlled, randomized postmarket U.S. study comparing discectomy patients who receive anular repair using Anulex's Xclose Tissue Repair System to those who have no repair. Arthro Kinetics (AKI) has also developed anular repair technologies, with an annulus closure device that could enter human studies in 2009. The company also expects to enter human trials in 2009 for its collagen matrix nucleus replacement device.

Enrollment was completed for Globus Medical's 380-patient enrollment for the SECURE-C Cervical Artificial Disc clinical trial, LDR's one- and two-level studies of the Mobi-C cervical artificial disc, Spinal Kinetics' 30-patient U.S. Feasibility Study of the M6-C cervical disc and Cervitech's multi-center PCM (Porous Coated Motion) Artificial Cervical Disc study. FDA also granted AOI Medical approval to begin a clinical trial of its AscendX vertebral compression fracture treatment and conditionally approved Interventional Spine's IDE application for the PercuDyn System for the treatment of degenerative disc disease.

Impliant will restart patient enrollment in its pivotal IDE trial of the TOPS Total Posterior Arthroplasty device. The company had voluntarily suspended its trial following the failure of one device due to device misalignment coupled with excessive shear loading. Minor design and manufacturing changes have been incorporated into the device.

Amid all the artificial disc activity, Ortoviva is developing an instrument, placement device and bone adhesive dispenser that together should facilitate insertion of artificial discs.

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U.S. regulatory status of motion preservation technologies appears in Exhibits 1 through 5.

Exhibit 1: Motion Preservation Landscape - Artificial Discs

CERVICAL			
Company	*Product*	*Description*	*Regulatory Status*
Abbott Spine	ISD	Elastomer core in woven cover; replaces anterior longitudinal ligament	
Amedica	Altia	Silicon nitride ceramic; anterior	IDE expected to begin 2009
Cervitech	PCM-V, PCM-TI, PCM-EF	CoCr or Ti on poly, broad radius, unconstrained; anterior	CE Mark; U.S. pivotal clinical trial enrollment complete
DePuy	Discover	Ti on poly; anterior	CE Mark; IDE began 2006
Disc Motion	TrueDisc-C		
Globus	Secure-C	Metal on poly/semi mobile bearing; anterior	IDE enrollment complete
LDR Spine	Mobi-C	Ti/HA coated CoCr on poly, mobile core, 6° of freedom; anterior	CE Mark; IDE enrollment complete
Medtronic	Prestige ST	Stainless steel metal on metal, ball and trough; anterior	CE Mark; FDA cleared
Medtronic	Prestige LP	Ceramic on ceramic, ball and trough; anterior	CE Mark; FDA cleared
Medtronic	Bryan	Ti on polyurethane, ball and socket; anterior	CE Mark; IDE ongoing; recommended for FDA clearance
Nexgen Spine	Physio-C	CoCr with Ti porous coated endplates + polycarbonate polyurethane core; anterior	
NuVasive	CerPass	Ceramic on ceramic; anterior	CE Mark; IDE expected to begin 2008
Orthofix	Advent	Ti on polyurethane, ball and socket; anterior	IDE began 2008
Pioneer Surgical	NuNec	HA-coated PEEK on PEEK semi-constrained ball and trough hybrid; anterior	CE Mark; 1st implant 2Q08; IDE expected to begin 2008
Rainer	CAdisc-C	Variable modulus elastomer; anterior	In development

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CERVICAL			
Company	*Product*	*Description*	*Regulatory Status*
Scient'x	DiscoCerv	Ceramic on ceramic; anterior	CE Mark; IDE expected to begin 2008
SeaSpine	Catalina	CoCr w/ PEEK endplates; anterior	IDE expected to begin 2008
Spinal Kinetics	M6	Polymeric nucleus, poly fiber annulus, Ti endplates; anterior	CE Mark; feasibility study underway
Spinal Motion	Kineflex C	CoCr on CoCr with CoCr mobile core; anterior	CE Mark; IDE enrollment complete
Stryker	Cervicore	CoCr on CoCr saddle; anterior	CE Mark; IDE began 2006; PMA application submission anticipated 2009
Synthes	ProDisc-C	CoCr on poly, ball and socket; anterior	CE Mark; FDA cleared
Takiron	Fabricube	Poly-L-lactide + polyethylene fibers	In development
Vertebron	CMP	CoCr on CoCr; anterior	In development
LUMBAR			
Company	*Product*	*Description*	*Regulatory Status*
Advanced Prosthetic Technologies		Resorbable steps, elastomeric polymer, Ti plugs and bellows; compressible	
Aesculap	Activ L	CoCr on poly, semi mobile bearing; anterior	CE Mark; IDE began 2007
AxioMed	Freedom	Elastomer/Ti endplates; anterior	IDE began 2008
Biomet	Min T	Ceramic on endplate, Ti keel fixed to vertebra; anterior or anterolateral	Trials in Australia
DePuy	Charité	CoCr on poly, ball and socket; anterior	CE Mark; FDA cleared
Disc Motion	TrueDisc-L	Ball and socket; posterior	CE Mark
Eden Spine	Welldisc-L	Stainless steel on poly; anterior	CE Mark expected in 2009
Eska Implants		Hemispherical cups w/ silicon core; anterior	
Globus	Alliance	CoCr on poly; posterior	In development

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LUMBAR			
Company	*Product*	*Description*	*Regulatory Status*
Globus	Triumph	CoCr on poly; transforaminal	In development
LDR Spine	Mobidisc	Ti/HA coated metal (CoCr) on poly, mobile core, 6° of freedom; anterior	CE Mark; IDE enrollment complete
Medtronic	A-Mav	CoCr on CoCr, ball and socket; anterior	CE Mark; IDE enrollment complete
Medtronic	O-Mav	CoCr on CoCr, ball and socket; anterior oblique	CE Mark
Nexgen Spine	Physio-L	CoCr with Ti porous coated endplates; polycarbonate polyurethane core; anterior or anterolateral	CE Mark
NuVasive	XL-TDR	CoCr on CoCr; eXtreme lateral	IDE expected to begin 2008
Ranier	CAdisc-L	Variable modulus elastomer; anterior	In development
SeaSpine	La Jolla		In development
Signus	Lyptic	Metal on metal; anterior	In development
Spinal Kinetics	M6	Polymeric nucleus, poly fiber annulus, Ti endplates; anterior	CE Mark; U.S. feasibility enrollment complete
Spinal Motion	Kineflex L	CoCr on CoCr with CoCr mobile core; anterior	CE Mark; IDE enrollment complete
Stryker	FlexiCore	CoCr on CoCr, constrained ball and socket; anterior	CE Mark; IDE enrollment complete
Synthes	ProDisc-L	CoCr on poly, ball and socket; anterior	CE Mark; FDA cleared
Theken Disc	eDisc	Elastomer/Ti endplates, w/electronics; anterior or anterolateral	In development
TranS1	PDR	Crosslinking elastomer; trans-sacral	Expects to begin human clinicals ex-U.S. 2008
Zimmer	Dynardi	CoCr on poly, mobile core; anterior	CE Mark

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Exhibit 2: Motion Preservation Landscape - Dynamic Stabilization

Company	*Product*	*Description*	*Clinical Status*
Abbott Spine	Wallis	Interspinous; PEEK spacers and clips, polyethylene braided "loops"	CE Mark; IDE began 2005
Applied Spine Technologies	Stabilimax NZ	Pedicle screw based	In IDE; enrollment completion expected 3Q09
Biomet	ISS	Interspinous	CE Mark
Custom Spine	ISSYS DC	Screw based nitinol springs/joints	
DePuy	PDS		CE Mark
Disc Motion Technologies	TrueDyne PDS	Rod based	FDA clearance expected 2008
Eden Spine	FX-1	Dynamic rod technology - pedicle screw based	FDA clearance expected 2009
Eden Spine	Wellex	Interspinous	CE Mark expected 2008; IDE expected 2010
Globus	Flexus	Interspinous; PEEK	In IDE; 1st implantation 8/08
GM Reis	Dinamika	Pedicle screw based	
GM Reis	Dynafix	Interspinous; Ti	
Innovative Spinal	Axient SC	Pedicle screw-based, adjunct to fusion	Pending FDA clearance
Innovative Spinal	Axient Total	Pedicle screw-based full motion posterior dynamic stabilization	IDE enrollment expected 2008
Interventional Spine	PercuDyn	Percutaneous bilateral facet augmentation system, including L5-S1	CE Mark; FDA conditional approval of IDE 2008
K2M	Potomac	Pedicle screw/rod based; nickel Ti	FDA clearance expected 2008
Life Spine	Dyna-Link	Rod/plate based	FDA cleared as fusion device
Medtronic	Aperius	Percutaneous interspinous; Ti alloy	CE Mark
Medtronic	DIAM	Interspinous; silicon + polyethylene	CE Mark; IDE began 2008
Medtronic	X STOP	Interspinous; Ti alloy	FDA cleared
Mekanika	Modulus System	Pedicle screw based; carbon fiber composite	In development
NuVasive	ExtenSure	Interspinous; allograft	FDA cleared
Paradigm Spine	coflex	Interspinous; Ti alloy	CE Mark; IDE began 2006

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Company	*Product*	*Description*	*Clinical Status*
Paradigm Spine	DSS	Pedicle screw based	CE Mark
Pioneer Surgical	BacJac	Self deploying interspinous spacer; PEEK on PEEK	CE Mark; IDE expected 1st half 2009
Privelop	Spinos	Interspinous; Ti	CE Mark
Scient'x	Aladyn	Rod and/or posterior plate based	CE Mark
Scient'x	Isobar Duo	Pedicle screw based; Ti or stainless steel	CE Mark; FDA cleared as fusion device
Scient'x	Isobar TTL Dynamic Rod	Pedicle screw based; Ti, shock absorber	CE Mark; FDA cleared as fusion device
Scient'x	Isolock	Posterior dynamic plate with washers	CE Mark; FDA cleared as fusion device
Scient'x	Twinflex	Pedicle screw based; Ti or stainless steel	CE Mark
SpineVision	FlexPLUS	Pedicle screw based; Ti and polymer	CE Mark
Synthes	In-Space	Interspinous	IDE began mid-2008
Synthes	Nflex	Pedicle screw based; Ti and elastomer	CE Mark; IDE began 2007
Vertebron	SPX	Spinous process spacer	In development
VertiFlex	Dynabolt	Pedicle screw based, adjunct to fusion	FDA cleared as fusion device
VertiFlex	Superion	Percutaneous interspinous; Ti	CE Mark; 1st U.S. implantation in 2008
Zimmer Spine	Dynesys	Screw based; polycarbonate urethane spacer + polyethylene terephthalate	CE Mark; IDE began 2003; FDA cleared as fusion device

Exhibit 3: Motion Preservation Landscape - Facet Arthroplasty

Company	*Product*	*Description*	*Regulatory Status*
Archus	TFAS	Replaces facets and posterior ligaments	CE Mark; in IDE; 1st human implantation in 2008
Facet Solutions	AFRS	Pedicle screw based + anatomically designed implants	CE Mark; pilot clinicals ongoing
Spinal Elements	Zyre	Malleable spacer between facets	First system implanted 2008

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Exhibit 4: Motion Preservation Landscape - Nucleus Replacement

Company	*Product*	*Description*	*Regulatory Status*
AKI		Collagen matrix	Preclinicals expected 2nd half 2008; human trials 2009
Biomet	Regain	One-piece pyrocarbon	CE Mark; MHRA (Japan) study underway; IDE feasibility enrollment underway
Corin	Percutaneous Disc Nucleus	Bag w/ gel	
CryoLife	BioDisc	Curable, *in situ* polymerizing protein hydrogel (purified bovine albumin + glutaraldehyde)	Submitted CE Mark 2007
DePuy Spine	SINUX ANR	Curable liquid polymer	CE Mark
Disc Dynamics	DASCOR	2-part flowable, curable polyurethane	CE Mark; pilot clinicals began 2006
Dynamic Spine	IPD	Annular sparing Intervertebral Prosthetic Disc	In development
Gentis	DiscCell	Injectable reverse emulsion polymer matrix	CE Mark filing and pivotal IDE expected in 2009
NP Solutions	RejuvaDisc	Self-hardening, injectable	In development
NuVasive	NeoDisc	Elastomeric core surrounded by embroidered jacket	IDE began 2006; completed enrollment expected 2008
Pioneer Surgical	NuBac	PEEK on PEEK intradiscal arthroplasty, two-piece articulating inner ball/socket	CE Mark; pilot clinicals complete
Raymedica	HydraFlex	Inert hydrogel core in flexible woven polyethylene jacket	CE Mark; IDE began 2006
Raymedica	PDN Solo	Inert hydrogel core in flexible woven polyethylene jacket	CE Mark
Replication Medical	NeuDisc	Modified poly-acrylonitrile polymer	Pilot clinicals ongoing
Spine Wave	NuCore	Injectable, 100% synthetic recombinant protein hydrogel	Pilot clinicals ongoing, pivotals expected to begin 2008
SpineMedica	SaluDisc	Salubria hydrogel	Pre-IDE meeting with FDA 2006
Stryker	Aquarelle	Polyvinyl alcohol hydrogel	In development
Synthes	Hydrafil	Gelifex injectable hydrogel	In preclinicals
TranS1	PNR	*In situ* crosslinking elastomer	CE Mark expected 2008; pilot clinicals in Europe 2008
Vertebral Technologies		Biocompatible polymers	In development
Zimmer	Newcleus		Pilot clinicals in Europe ongoing

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Exhibit 5: Motion Preservation Landscape - Other Technologies

Company	*Product*	*Description*	*Regulatory Status*
Disc Motion	True Total Spinal Motion Segment System	Total spinal joint replacement – posterior lumbar disc + dynamic stabilizer + dynamic screw	CE Mark; 1st human implantation June 2008
Flexuspine	FSU	Functional Spinal Unit	
Impliant	TOPS	Total posterior arthroplasty; pedicle screw-based, semi-constrained Ti construct w/ central articulating core	CE Mark; IDE began 2006
Paradigm Spine	Orthobiom	Non-fusion for adolescent idiopathic scoliosis; commonly used orthopaedic materials	In preclinicals

In third quarter 2008, Spinal Restoration completed enrollment of patients in its IDE pilot study of the Biostat Disc Augmentation System, which comprises Biostat Biologx Fibrin Sealant and a delivery system. The resorbable biologic technology applies Biologx into a disrupted disc to occlude annular fissures and lay down tissue repair matrix. The company believes that this novel biological solution could relieve pain by sealing off annular fissures from inflammatory substances contained in the disc nucleus. This author finds it to be a particularly exciting technology.

I find FzioMed's Oxiplex/SP Gel exciting, as well, if only for its potential to help U.S. spine surgeons deal with the problem of adhesions. So, I was a bit taken aback by the FDA panel's recent recommendation not to approve the product. Cleared in 49 countries and used in more than 100,000 surgeries to date, Oxiplex is applied around the spinal nerve root and surrounding neural tissues during lumbar laminectomy, laminotomy and discectomy with the intent to create a protective environment during healing and to improve patient outcomes by reducing postoperative leg and back pain and neurological symptoms. FDA had granted the product expedited review status, since no other products are available in the U.S. to reduce residual pain and symptoms post-op. However, the panel determined that the product did not demonstrate a statistically significant treatment benefit. FzioMed will schedule a meeting with FDA to move forward in trying to resolve questions raised by the panel.

In the realm of materials, coLigne received FDA clearance for a vertebral body replacement (VBR) made from its ostaPek highly dense, long carbon fiber reinforced polymer. A number of PEEK Optima VBRs also gained regulatory clearance for Creaspine (distributed by SpineSource), LDR and Signus, while PEEK comprised the material for intervertebral body fusion devices from Innovative Spinal Technologies and Spinal Elements. Signus took the technology a bit farther with its Kimba Mini system for transforaminal fusion, which incorporates radiolucent Endless Carbon Fiber-reinforced PEEK Optima manufactured by Icotec.

FDA cleared BME's nitinol-based OSSpine dynamic residual compression implant for use in anterior fixation of the cervical spine, while Amedica's clearances from FDA centered on the company's Valeo line, which features not only cervical plate and pedicle screw, but also a silicon nitride ceramic VBR. And, in resorbables, Inion received FDA clearance to market its S-1 Anterior Cervical Fusion, S-1 double-level plate and S-2 Anterior Thoraco-Lumbar Fusion biodegradable systems for graft containment in spinal fusion procedures.

With an FDA clearance for expanded use of the SpineAssist imaging and robotic device in cervical and minimally invasive procedures, Mazor Surgical Technologies' customers can now place the device on the surgical table instead of on the patient, which the company believes may be key for its use in the GO-LIF procedure.

FDA cleared a few dynamized systems (but not for dynamic stabilization) – Life Spine's Kinetic-SL dynamized anterior cervical plating system, the Isobar DUO Dynamic Stabilization System from Scient'x and Alphatec's Dynamo Rod System.

Other clearances include rod/screw systems from Alphatec, Life Spine, Pioneer, Signus, Theken, VertiFlex and X-Spine, with plating systems from X-Spine, interbody fusion devices from RSB Spine and Vertebral Technologies and the two-level AxiaLIF from TranS1. Finally, FDA blessed StemCor Systems' MarrowMiner for use in the harvesting of bone marrow and expanded Titan Spine's 510(k) for the Endoskeleton TA VBR to include an interbody fusion device indication.

Of the companies mentioned in the preceding paragraphs, only Creaspine and Vertebral Technologies are newcomers to the FDA clearance list. They, along with Accin, Biospine, bk Meditech, ChoiceSpine, Corelink, Elite Surgical Suppliers, G Surgical, Kiscomedica, Neurospine Innovations and Solutions, New Business Development, Reliance Medical, Spine Select, SpineSmith Partners, SpineFrontier and Titan Spine boast first time clearances for spine products through FDA's Orthopaedic panel.

Product News

In concert with FDA clearances, numerous companies brought out new products in the U.S. Market-leading Medtronic expanded its CD Horizon line with introductions of the Legacy Anterior Spinal System and a Multi-level Percutaneous Fixation System, part of the company's Minimal Access Spinal Technologies portfolio. The market also saw launches of VBR devices from LDR and DePuy Spine; interbody fusion and anterior lumbar plates from Vertebron; cervical plates from DePuy

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(Eagle Plus Rigid and Swift Plus Dynamic systems), K2M (Pyrenees), NuVasive (Helix and Helix MiniPlate) and Pioneer (SlimFuse); pedicle screw/rod systems from Alphatec (Dynamo Semi-Rigid Spinal System); K2M (Range Rigid Rod), NuVasive (SpheRx DBR II), Spinal Elements (Mercury) and SpineVision (FlexPLUS Rod and PediGuard MIS Sleeve); a corpectomy spacer from Globus and PEEK-Optima products from Atlas Spine (VBR), DePuy Spine (Expedium rods), K2M (lumbar spacers), LDR (partial VBRs) and NuVasive. Brand new to the market is VG Innovations, which launched the VerteLoc minimally invasive facet stabilization system and instrumentation.

Altiva (now Exactech) announced the 100th implantation of its ALTES Anterior Buttress Plate and the year saw the first implantation of RSB Spine's InterPlate L in the lumbar spine and SIGNUS Medical's first surgery using the TOSCA II Anterior Cervical Plating System. RSB also completed its U.S. rollout of the InterPlate C, while Interventional Spine reached its own milestone with the training of the 400th physician on its percutaneous spine therapy technologies.

Novel instruments entered the market through launches from HydroCision (SpineJet XL oval tip instruments), ArthroCare (Parallax Contour osteotome and MD SpineWand), Atlas Spine (discectomy set), joimax (360° TESSYS and the iLESSYS systems for the treatment of spinal canal stenosis) and Mazor Surgical Technologies (SpineAssist for cervical applications and bed mounted miniature robotic device intended for use in mono-segmental minimally invasive cases). Mazor also expects to introduce its C-InSight, a software program that converts existing C-arms into a 3-dimensional imaging system for the OR. In time, CoreSpine hopes to enter the market with nucleus removal devices. The company expanded its technology recently to include a cartilage removal device that would address endplate preparation.

M&A Activity and Funding

In the midst of all the product launches and FDA clearances, Alphatec Spine repositioned itself as a company focused on treating conditions related to the aging spine. Two agreements in particular will help Alphatec achieve its new mission – Stout Medical for commercialization of the OsseoFix system (formerly V-Stent), a minimally invasive expandable titanium cage for the treatment of vertebral fractures and Progressive Spinal Technologies for co-development and commercialization of an osteoporotic pedicle screw technology.

Alliances kept SpineSource busy, as well. Through exclusive agreements, the company now handles U.S. distribution for Anatomica (Olerud MK2 Posterior Cervical Fixation System), Advanced Medical Technologies (PEEK Optima-based interbody fusion products), A-Spine (anterior thoracolumbar fixation plating system) and Creaspine (PEEK spinal implant).

In keeping with its focus on treating patients with internal disc derangement, SpineOvations entered into an agreement to acquire from Discogen certain technology for intradiscal drug delivery which could complement its percutaneous injectable DiscSeal agent. Orthofix acquired the rights to all intellectual property related to the InSWing interspinous process spacer, Synthes agreed to acquire N Spine whose products treat lumbar spinal disorders using posterior dynamic stabilization and DePuy Spine bought certain assets from Disc-O-Tech Medical Technologies including the Confidence System for delivery of bone cement and next-generation vertebral compression fracture technologies.

On the acquisition front, NuVasive filled out its matrix of products with its purchase of Osiris' Osteocel biologics business and Integra made headline news with its purchase of Theken Spine, Theken Disc and Therics. Just a few years ago, Integra's spinal portfolio centered on pain management and cement delivery systems, not "traditional" spine company products. Within the span of 18 months, the company developed and launched its own bone graft products and purchased IsoTis and now Theken.

Looking at the money side of things, TranS1's initial public offering brought in more than $86 million, leading the spine field in fund raising. Financial support came, as well, to Paradigm Spine, which raised $39 million in early 2008. The company will use the funds to support U.S. sales of its DSS pedicle screw-based system and an ongoing IDE trial of the coflex device in the treatment of spinal stenosis.

VertiFlex, whose products include traditional fusion devices as well as an interspinous spacer and dynamic stabilization rod, brought in $28.3 million in venture funding, while Vertos Medical closed a $12 million Series C financing round. The latter seeks to launch its FDA-cleared MILD (Minimally Invasive Lumbar Decompression) devices.

Spinal Restoration closed a $16 million Series B financing round, giving it much-needed funds to support the IDE trial of its Biostat disc augmentation technology. Ranier Technology secured $16 million, as well, and will use the money to support clinical testing and European launch of its CAdisc disc replacement products. Benvenue Medical's $15 million in Series B funds will help that company further develop flexible VCF implant technology and gain regulatory clearance and clinical experience with the technology. An infusion of $7.5 million in financing for Spineology will be used to support commercialization, product development and clinical research. With its $4 million in funding, OuroBoros hopes to further the development of a minimally invasive spinal fusion device, while SpineSource's $1.2 million infusion will support distribution of spinal products in the U.S. Some $1.1 million will help OrthoData enter clinical trials with its diagnostic system that monitors the progress of spinal fusion via a sensor placed on an implanted metal rod to measure strain.

DePuy Spine and Johnson & Johnson Development Corporation contributed $5 million in Series C equity financing to Biomerix for further development of an annular repair implant, which features a biocompatible, biodurable polyurethane scaffold that has demonstrated the support of tissue growth in animals. Finally, Axial Biotech not only closed a $6 million tranche in Series B funding, but also met some milestones in the development of its first genetic prognostic test for Adolescent Idiopathic Scoliosis. The company could launch the test sometime this year.

To summarize…enough cervical plates, pedicle screw systems and VBRs to sink a battleship. More than 40 discs and as many dynamic stabilization devices. A highly competitive environment in which ten companies control the business (although the two largest are losing market share).

Then consider…more than $230 million raised in a year and nearly 20 brand new companies with FDA clearance.

Seems kind of counterintuitive, doesn't it? – all this action in a market whose growth is slowing and whose landscape is beyond crowded. But, no other segment of the orthopaedic market attracts so much interest or investment. Spine is still hot, ain't no denying. It won't stay that way forever, though. I think the best we can hope is that all the money being put into the space brings a healthy return on investments – mine and everyone else's.

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