Spinal Surgery Devices Market to 2018

New Entrants and Technological Advances to Intensify Competition in the Spinal Fusion Segment







GBI Research Report Guidance

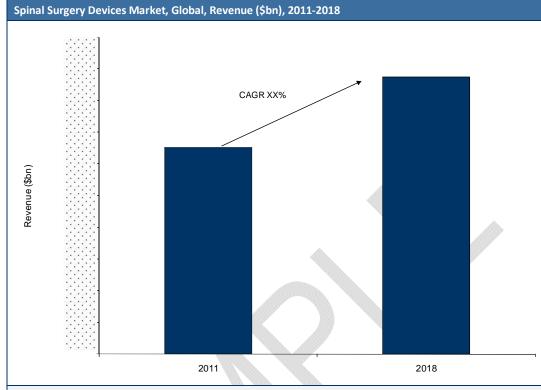
- The report begins with an executive summary capturing the key points that determine the dynamics of the spinal surgery devices market. Competition in the industry and key segments and geographical regions are also outlined.
- Chapter four provides information on market size for the 2004-2011 historic period and the 2011-2018
 forecast period. It also has information relating to spinal surgery devices market trends, market
 dynamics and the competitive landscape. In the market dynamics section, comprehensive information
 is provided on market drivers and restraints.
- Chapter five discusses spinal fusion and spinal non-fusion segments, and gives information on market size for the 2004-2011 historic period and the 2011-2018 forecast period, as well as information on market dynamics and competition. However, company shares for the segments have not been covered.
- Chapter six gives information on market size for the 2004-2011 historic period and the 2011-2018 forecast period for the US, Canada, the UK, France, Germany, Italy, Spain, Japan, China, India, Australia and Brazil, as well as a cross-country analysis of each.
- Chapter seven profiles the leading spinal surgery device companies and looks at their products' features and benefits.
- Chapter eight focuses on the pipeline products in the two segments. Key pipeline products are listed
 and discussed in detail and product approval and expected launch dates are provided where available.
- Chapter nine discusses the consolidation landscape in the spinal surgery devices industry, and looks at the deals that took place between 2007 and 2011



Executive Summary

The Global Spinal Surgery Devices Market is Forecast to Increase by XX% over the Forecast Period

The global spinal surgery devices market is expected to increase from \$XX billion in 2011 to \$XX billion in 2018, driven by a large patient pool and an increase in procedure volumes



Source: GBI Research' s proprietary database [accessed on October 31, 2012]; primary research interviews with marketing managers and other industry experts

The global spinal surgery devices market is expected to grow at a Compound Annual Growth Rate (CAGR) of XX% during the 2011-2018 period from \$XX billion in 2011 to \$XX billion in 2018. An increasing preference for Minimally Invasive Spinal Surgery (MISS) is resulting in a high demand for spinal surgery devices. A large patient pool due to a rapidly growing elderly population and an increase in the spinal surgery procedure volumes, are important factors driving the global spinal surgery devices market.

Increasing Demand for Minimally Invasive Spinal Surgeries to Increase Adoption of Spinal Surgery Devices

MISS is rapidly finding acceptance as it has a number of clinical benefits over traditional open-spinal surgery and can be used to treat conditions such as disc herniation, spinal stenosis, degenerated disc diseases and compression fractures, among others. Spinal deformities and instability can also be rectified using the minimally invasive approach.

Open spinal surgeries are associated with a number of drawbacks, namely large incision scars and surgical complications such as excessive blood loss and severe post-operative pain, all of which lead to longer hospital stays and a longer overall recovery period.

These shortcomings can be minimized or eliminated through MISS techniques, which require an incision of only XXcm. It uses advanced techniques and devices such as endoscopes, lasers and sophisticated computer-aided navigation systems to minimize the risk of unwanted adverse events such as severe blood loss and tissue injury.



1 Table of Contents

1	Table	of Co	ntents	5
	1.1	List	of Tables	8
	1.2	List	of Figures	10
2	Introd	uctio	n	11
3	Spinal	Surg	ery Devices - Overview	12
	3.1	Spin	al Fusion Devices	12
	3.2	Spin	al Non-Fusion Devices	12
4	Spinal	Surg	ery Devices - Market Characterization	13
	4.1	Glob	oal Spinal Surgery Devices Market, Revenue (\$m), 2004-2011	13
	4.2	Glob	oal Spinal Surgery Devices Market, Revenue (\$m), 2011-2018	14
	4.3		oal Spinal Surgery Devices Market, Key Company Share (%), 2011	
	4.4		pal Spinal Surgery Devices: Key Trends	
	4.4.	1	Physician-Owned Distributorship Models Experience a Decline in the Spinal Surgery Mark	æt
	4.4.	2	Competition Expected to Increase as Companies Capitalize on Technological Advances in	the
			Spinal Fusion Market	
	4.5	Glob	oal Spinal Surgery Devices: Market Dynamics	
	4.5.	1	Market Drivers	19
	4.5.	2	Market Restraints	22
5	Global	Spin	al Surgery Devices Market - Segment Analysis and Forecasts	24
	5.1	Glob	oal Spinal Fusion Devices Market, Revenue (\$m), 2004-2011	24
	5.2		oal Spinal Fusion Devices Market, Revenue (\$m), 2011-2018	
	5.3	Glob	pal Spinal Fusion Devices: Market Dynamics	
	5.3.	1	Market Drivers	26
	5.3.	2	Market Restraints	27
	5.4		oal Spinal Non-Fusion Devices Market, Revenue (\$m), 2004-2011	
	5.5		oal Spinal Non-Fusion Devices Market, Revenue (\$m), 2011-2018	
	5.6	Glob	oal Spinal Non-Fusion Devices: Market Dynamics	
	5.6.	1	Market Drivers	
	5.6.	_	Market Restraints	
6	Global		al Surgery Devices Market - Country Analysis and Forecasts	
	6.1		al Surgery Devices Market: Cross-country Analysis	
	6.2	Hist	oric and Forecast Revenue, By Country	
	6.2.		Spinal Surgery Devices Market, US, Revenue (\$m), 2004-2011	
	6.2.	2	Spinal Surgery Devices Market, US, Revenue (\$m), 2011-2018	
	6.2.		Spinal Surgery Devices Market, Japan, Revenue (\$m), 2004-2011	
	6.2.		Spinal Surgery Devices Market, Japan, Revenue (\$m), 2011-2018	
	6.2.		Spinal Surgery Devices Market, Germany, Revenue (\$m), 2004-2011	
	6.2.		Spinal Surgery Devices Market, Germany, Revenue (\$m), 2011-2018	
	6.2.	7	Spinal Surgery Devices Market, China, Revenue (\$m), 2004-2011	
	6.2.		Spinal Surgery Devices Market, China, Revenue (\$m), 2011-2018	
	6.2.		Spinal Surgery Devices Market, UK, Revenue (\$m), 2004-2011	
	6.2.		Spinal Surgery Devices Market, UK, Revenue (\$m), 2011-2018	
	6.2.	11	Spinal Surgery Devices Market, Spain, Revenue (\$m), 2004-2011	46
	6.2.		Spinal Surgery Devices Market, Spain, Revenue (\$m), 2011-2018	
	6.2.	13	Spinal Surgery Devices Market, France, Revenue (\$m), 2004-2011	
	6.2.	14	Spinal Surgery Devices Market, France, Revenue (\$m), 2011-2018	49
	6.2.	15	Spinal Surgery Devices Market, Italy, Revenue (\$m), 2004-2011	
	6.2.		Spinal Surgery Devices Market, Italy, Revenue (\$m), 2011-2018	
	6.2.	17	Spinal Surgery Devices Market, Australia, Revenue (\$m), 2004-2011	52



	6.2.18	Spinal Surgery Devices Market, Australia, Revenue (\$m), 2011-2018	53
	6.2.19	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2004-2011	54
	6.2.20	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2011-2018	55
	6.2.21	Spinal Surgery Devices Market, Canada, Revenue (\$m), 2004-2011	56
	6.2.22	Spinal Surgery Devices Market, Canada, Revenue (\$m), 2011-2018	57
	6.2.23	Spinal Surgery Devices Market, India, Revenue (\$m), 2004-2011	58
	6.2.24	Spinal Surgery Devices Market, India, Revenue (\$m), 2011-2018	59
7	Global Spin	al Surgery Devices Market - Competitive Assessment	60
	7.1 Med	dtronic	61
	7.1.1	Business Overview	61
	7.1.2	Products Marketed	61
	7.2 DeP	uy Synthes	62
	7.2.1	Business Overview	62
	7.2.2	Products Marketed	
	7.3 Stry	ker	
	7.3.1	Business Overview	63
	7.3.2	Products Marketed	63
	7.4 NuV	/asive	
	7.4.1	Business Overview	64
	7.4.2	Products Marketed	64
	7.5 Orth	nofix	65
	7.5.1	Business Overview	
	7.5.2	Products Marketed	65
	7.6 Zim	mer Holdings	
	7.6.1	Business Overview	
	7.6.2	Products Marketed	
	7.7 Glol	bus Medical	
	7.7.1	Business Overview	
	7.7.2	Products Marketed	
	7.8 Alph	natec Holdings	
	7.8.1	Business Overview	
	7.8.2	Products Marketed	
	7.9 B. B	raun Medical	69
	7.9.1	Business Overview	
	7.9.2	Products Marketed	
8	Global Spin	al Surgery Devices Market - Product Pipeline Analysis	
		nal Fusion Devices: Product Pipeline	
	8.1.1	Spinal Fusion Devices: Profiles of Key Pipeline Products	
	8.1.2	Spinal Fusion Devices: List of Pipeline Products	
		nal Non-Fusion Devices: Product Pipelin	
	8.2.1	Spinal Non-Fusion Devices: Profiles of Key Pipeline Products	
	8.2.2	Spinal Non-Fusion Devices: List of Pipeline Products	
9		al Surgery Devices Market - Consolidation Landscape	
		nal Surgery Devices Market: Number of Deals and Deal Value, 2007-2011	
	-	Deals: 2007-2011	
	9.2.1	Globus Medical's Acquisition of Facet Solutions	
	9.2.2	Alphatec Spine's Acquisition of Scient'x Groupe	
	9.2.3	NuVasive's Acquisition of Cervitech	
	9.2.4	Zimmer Holdings' Acquisition of Abbott Spine from Abbott Labs	
	9.2.5	Regeneration Technologies' Acquisition of Tutogen Medical	
	9.2.6	Medtronic's Acquisition of Kyphon	
10		Weditonic 3 Acquisition of Kyphon	
_0	ppciidix ii		



10.1	Defir	nitions	92
10.1	1.1	Spinal Surgery Devices	92
		nyms	
		, Ces	
10.4	Rese	arch Methodology	96
10.4	4.1	Secondary Research	96
10.4	4.2	Primary Research	96
10.4	4.3	Models	97
10.4	4.4	Forecasts	97
10.4	4.5	Expert Panels	97
		act Us	
10.6	Diccl	aimar	00





1.1 List of Tables

Table 1:	Global Spinal Surgery Devices Market, Revenue (\$m), 2004-2011	
Table 2:	Global Spinal Surgery Devices Market, Revenue (\$m), 2011-2018	
Table 3:	Global Spinal Surgery Devices Market, Key Company Share (\$m), 2011	
Table 4:	Global Spinal Surgery Market, Physician-Owned Distributorships Models	16
Table 5:	Global Spinal Surgery Market, Minimally Invasive Spinal Fusion Techniques and Developing	
	Companies	
Table 6:	Spinal Surgery Devices Market, Population Aged above 60, Top 12 Countries, 2010	
Table 7:	Global Spinal Fusion Devices Market, Revenue (\$m), 2004-2011	
Table 8:	Global Spinal Fusion Devices Market, Revenue (\$m), 2011-2018	
Table 9:	Global Spinal Non-Fusion Devices Market, Revenue (\$m), 2004-2011	
Table 10:	Global Spinal Non-Fusion Devices Market, Revenue (\$m), 2011-2018	
Table 11:	Spinal Non-Fusion Devices Market, Examples of Commercially Available Products	
Table 12:	Spinal Surgery Devices Market, Cross-country Analysis, Global, CAGR (%), 2004-2018	
Table 13:	Spinal Surgery Devices Market, US, Revenue (\$m), 2004-2011	
Table 14:	Spinal Surgery Devices Market, US, Revenue (\$m), 2011-2018	
Table 15:	Spinal Surgery Devices Market, Japan, Revenue (\$m), 2004-2011	
Table 16:	Spinal Surgery Devices Market, Japan, Revenue (\$m), 2011-2018 Spinal Surgery Devices Market, Germany, Revenue (\$m), 2004-2011	
Table 17: Table 18:	Spinal Surgery Devices Market, Germany, Revenue (\$m), 2011-2018	
Table 19:	Spinal Surgery Devices Market, Germany, Revenue (\$m), 2011-2018	
Table 19.	Spinal Surgery Devices Market, China, Revenue (\$m), 2011-2018	
Table 20.	Spinal Surgery Devices Market, UK, Revenue (\$m), 2004-2011	
Table 22:	Spinal Surgery Devices Market, UK, Revenue (\$m), 2011-2018	
Table 23:	Spinal Surgery Devices Market, Spain, Revenue (\$m), 2004-2011	
Table 24:	Spinal Surgery Devices Market, Spain, Revenue (\$m), 2011-2018	
Table 25:	Spinal Surgery Devices Market, France, Revenue (\$m), 2011 2010	
Table 26:	Spinal Surgery Devices Market, France, Revenue (\$m), 2011-2018	
Table 27:	Spinal Surgery Devices Market, Italy, Revenue (\$m), 2004-2011	
Table 28:	Spinal Surgery Devices Market, Italy, Revenue (\$m), 2011-2018	
Table 29:	Spinal Surgery Devices Market, Australia, Revenue (\$m), 2004-2011	
Table 30:	Spinal Surgery Devices Market, Australia, Revenue (\$m), 2011-2018	
Table 31:	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2004-2011	
Table 32:	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2011-2018	
Table 33:	Spinal Surgery Devices Market, Canada, Revenue (\$m), 2004-2011	
Table 34:	Spinal Surgery Devices Market, Canada, Revenue (\$m), 2011-2018	57
Table 35:	Spinal Surgery Devices Market, India, Revenue (\$m), 2004-2011	58
Table 36:	Spinal Surgery Devices Market, India, Revenue (\$m), 2011-2018	59
Table 37:	Medtronic, Key Marketed Products, 2012	61
Table 38:	DePuy Synthes, Key Marketed Products, 2012	
Table 39:	Stryker, Key Marketed Products, 2012	
Table 40:	NuVasive, Key Marketed Products, 2012	
Table 41:	Orthofix, Key Marketed Products, 2012	
Table 42:	Zimmer, Key Marketed Products, 2012	
Table 43:	Globus Medical, Key Marketed Products, 2012	
Table 44:	Alphatec Medical, Key Marketed Products, 2012	
Table 45:	B. Braun Medical Inc., Key Marketed Products, 2012	
Table 46:	CleanFUZE, Product Status, 2012	
Table 47:	Interfuse Lateral System, Product Status, 2012	
Table 48:	C-Varlock, Product Status, 2012	
Table 49:	OsseoScrew Spinal Fixation System, Product Status, 2012	
Table 50:	XPED Expanding Pedicle Screw System, Product Status, 2012	
Table 51:	Pioneer QUANTUM Spinal Rodding System, Product Status, 2012	
Table 52:	ACADIA Facet Replacement System, Product Status, 2012	
Table 53:	Barricaid ARD, Product Status, 2012	
Table 54: Table 55:	FLEXUS Interspinous Spacer, Product Status, 2012	
Table 55:	IntelliRod System, Product Status, 2012	
i abie 30.	Spinal Lusion Devices. Giobal Fibellie Fibuucis, 2012, Idbie 1	/3



Table 57:	Spinal Fusion Devices, Global Pipeline Products, 2012, Table 2	76
Table 58:	Spinal Fusion Devices, Global Pipeline Products, 2012, Table 3	77
Table 59:	NuNec Cervical Arthroplasty Device, Product Status, 2012	78
Table 60:	M6-C Artificial Cervical Disc, Product Status, 2012	78
Table 61:	M6-L Artificial Cervical Disc, Product Status, 2012	79
Table 62:	Kineflex/C Imaging, Product Status, 2012	79
Table 63:	PercuDyn System, Product Status, 2012	80
Table 64:	BacJac System, Product Status, 2012	80
Table 65:	Coflex, Product Status, 2012	81
Table 66:	GelFix Interspinous Spacer, Product Status, 2012	81
Table 67:	Helifix Interspinous Spacer System, Product Status, 2012	81
Table 68:	GelStix, Product Status, 2012	82
Table 69:	Inlign TMS, Product Status, 2012	82
Table 70:	Spinal Non-Fusion Devices, Global Pipeline Products, 2012, Table 1	83
Table 71:	Spinal Non-Fusion Devices, Global Pipeline Products, 2012, Table 2	84
Table 72:	Spinal Non-Fusion Devices, Global Pipeline Products, 2012, Table 3	85
Table 73.	Spinal Surgery Devices Market: Number of Deals and Deal Value 2007-2011	86



1.2 List of Figures

Figure 1:	Global Spinal Surgery Devices Market, Revenue (\$m), 2004-2011	13
Figure 2:	Global Spinal Surgery Devices Market, Revenue (\$m), 2011-2018	
Figure 3:	Global Spinal Surgery Devices Market, Key Company Share (%), 2011	15
Figure 4:	Global Spinal Surgery Market, Strategic Acquisitions and Partnership Details	18
Figure 5:	Global Spinal Surgery Market, Minimally Invasive Spinal Fusion Techniques	19
Figure 6:	Spinal Surgery Devices Market, Population above 60 vs. Spinal Surgery Devices Volume	
	(Absolute Units), Top 12 Countries, 2010	
Figure 7:	Global Spinal Fusion Devices Market, Revenue (\$m), 2004-2011	
Figure 8:	Global Spinal Fusion Devices Market, Revenue (\$m), 2011-2018	
Figure 9:	Global Spinal Fusion Devices Market, Spinal Fusion Procedures, Global, 2010-2016	26
Figure 10:	Global Spinal Non-Fusion Devices Market, Revenue (\$m), 2004-2011	28
Figure 11:	Global Spinal Non-Fusion Devices Market, Revenue (\$m), 2011-2018	29
Figure 12:	Spinal Surgery Devices Market, Cross-country Analysis, Global, CAGR (%), 2004-2018	34
Figure 13:	Spinal Surgery Devices Market, US, Revenue (\$m), 2004-2011	
Figure 14:	Spinal Surgery Devices Market, US, Revenue (\$m), 2011-2018	37
Figure 15:	Spinal Surgery Devices Market, Japan, Revenue (\$m), 2004-2011	38
Figure 16:	Spinal Surgery Devices Market, Japan, Revenue (\$m), 2011-2018	39
Figure 17:	Spinal Surgery Devices Market, Germany, Revenue (\$m), 2004-2011	40
Figure 18:		
Figure 19:	Spinal Surgery Devices Market, China, Revenue (\$m), 2004-2011	42
Figure 20:	Spinal Surgery Devices Market, China, Revenue (\$m), 2011-2018	43
Figure 21:		
Figure 22:	, , , , , , , , , , , , , , , , , , , ,	
Figure 23:		
Figure 24:		
Figure 25:	Spinal Surgery Devices Market, France, Revenue (\$m), 2004-2011	48
Figure 26:	Spinal Surgery Devices Market, France, Revenue (\$m), 2011-2018	
Figure 27:	1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Figure 28:	, , ,	
Figure 29:	, , , , , , , , , , , , , , , , , , , ,	
Figure 30:	Spinal Surgery Devices Market, Australia, Revenue (\$m), 2011-2018	
Figure 31:	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2004-2011	
Figure 32:	Spinal Surgery Devices Market, Brazil, Revenue (\$m), 2011-2018	55
Figure 33:		
Figure 34:		
Figure 35:		
Figure 36:	Spinal Surgery Devices Market, India, Revenue (\$m), 2011-2018	59
	Global Spinal Surgery, Competitive Assessment, 2011	
Figure 38:	Spinal Surgery Devices Market: Number of Deals and Deal Value, 2007-2011	86



2 Introduction

Spinal surgery devices are used for the treatment of low back pain caused by various spinal pathologies such as degenerative disorders, spinal fractures, trauma, and sports injuries. The market for spinal surgery devices is driven by a number of factors such as a rapidly aging population, technological advances in spinal surgery techniques and an increasing preference for Minimally Invasive Spinal Surgery (MISS).

Spinal fusion surgery is the major revenue-generating segment in the spinal surgery market, with greater adoption by both surgeons and patients due to safer procedure outcomes, faster recovery and availability of clinical information. Improving medical reforms in the US and in developing countries such as China are additionally resulting in increased health insurance coverage, leading to an increase in procedure volumes.

Spinal non-fusion procedures are motion-preserving techniques employed when preserving motion is of particular importance, such as in cervical surgeries. Artificial Disc Replacements (ADRs) are now seeing more adoption as a result of a gradual shift in surgeon preference for spinal non-fusion procedures, due in turn to factors such as maintenance of mobility in patients undergoing spinal non-fusion surgeries and an increase in supportive clinical data driving adoption.

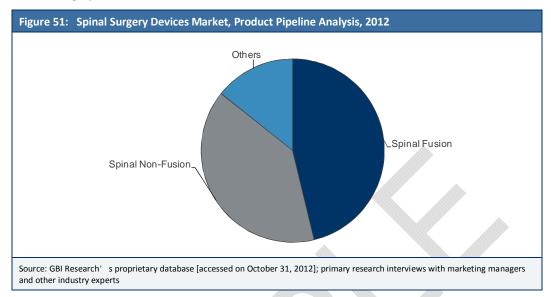




The global spinal surgery devices market comprises XX products in the pipeline with the majority in the spinal fusion segment

8 Global Spinal Surgery Devices Market - Product Pipeline Analysis

The following figure shows the percentage of pipeline products in each segment of the spinal surgery devices category.

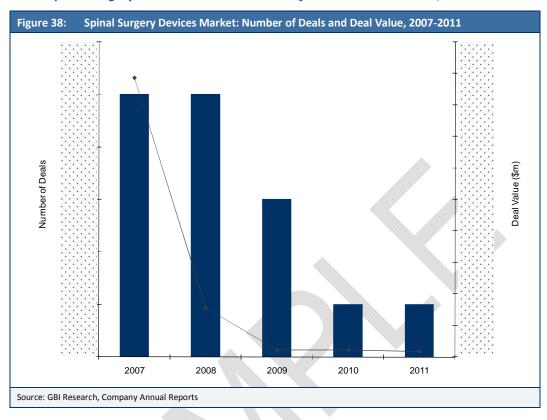


The global spinal surgery devices market comprises XX products in the pipeline with the majority in the spinal fusion segment (XX products accounting for approximately XX% of the pipeline). Surgeon preference for less complicated spinal fusion procedures and technology advances is resulting in a number of companies developing products based on the spinal fusion technology platform. Spinal non-fusion makes up XX% of total pipeline products, with other spinal surgery devices accounting for XX'%.



9 Global Spinal Surgery Devices Market - Consolidation Landscape

9.1 Spinal Surgery Devices Market: Number of Deals and Deal Value, 2007-2011



	2007	2008	2009	2010	2011
Number of deals					
Deal value					

The global spinal surgery market saw XX deals in the 2007-2011 period. Although not high, it is nonetheless significant as they accounted for a total value of \$XXm, attributed to the various market opportunities and strategic agreements that took place. A growing demand for technologically advanced products and a large patient pool are expected to lead to intense competition and drive M&A activity in the spinal surgery market.



10 Appendix

10.1 Definitions

10.1.1 Spinal Surgery Devices

Spinal surgery devices include devices used in the surgical treatment of diseases such as DDDs, intravertebral fractures and scoliosis. Spinal fusion and non-fusion devices are included in this category.

10.1.1.1 Spinal Fusion

Spinal fusion is a surgical procedure that involves joining two vertebrae in the spine using certain devices in order to relieve pain. Interbody cages, pedicle screw systems and spinal plating systems are covered under this segment.

Interbody Cages

Interbody cage fusion uses a hollow threaded titanium or carbon fiber cylinder to fuse two vertebrae together to treat DDD. During the process the diseased disc is removed and two interbody cages are placed in the opening. One unit consists of one cage

Pedicle Screw Systems

Pedicle screws are used in spinal fusion procedures to provide extra support and strength to the fusion while it heals. They are placed above and below the vertebrae and are made from a variety of materials such as stainless steel, titanium alloys, and unalloyed titanium. The device consists of a combination of anchors (such as bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (such as plates, rods, and/or plate/rod combinations); and/or transverse connectors. One unit consists of four screws, two rods and anchors such as bolts and hooks.

Spinal Plating Systems

Spinal plating system is an implant used to treat patients with DDD affecting the spine. One unit consists of two plates and four screws.

10.1.1.2 Spinal Non-Fusion

Spinal non-fusion surgery involves restoring spinal mobility by implanting an artificial disc in place of the diseased or damaged disc. The devices covered under this category are ADRs, dynamic stabilization and IPD devices.

Artificial Disc Replacement

ADR or disc arthroplasty is a surgical procedure during which an artificial disc replaces degenerated intervertebral discs. It is used both for the cervical spine and lumbar spine. One unit consists of one artificial disc

Dynamic Stabilization

Dynamic stabilization systems include a superior component for attachment to a superior vertebra of a spinal motion segment and an inferior component for attachment to an inferior vertebral of a spinal motion segment. One unit refers to one dynamic stabilization device.

Interspinous Process Decompression Devices

IPD is a surgical procedure in which an implant is placed between spinous processes in the back of the spine. They are mostly used for spinal stenosis procedures. One unit refers to one IPD device.



10.2 Acronyms

ADR: Artificial Disc Replacement

ALIF: Axial Lateral Interbody Fusion

ASD: Adjacent-Segment Degeneration

BMP-2: Bone Morphogenetic Protein-2

CAGR: Compound Annual Growth Rate

CRDM: Cardiac Rhythm Disease Management

DDD: Degenerative Disc Disease

DLIF: Direct Lateral Interbody Fusion

FBSS: Failed Back Surgery Syndrome

FDA: Food and Drug Administration

HPAN: Hydrolyzate Polyacrylonitrile

IDE: Investigational Device Exemption

IPD: Interspinous Process Decompression

LADR: Lumbar Artificial Disc Replacement

LIF: Lateral Interbody Fusion

LSS: Lumbar Spinal Stenosis

MAS: Maximum Access Surgery

MIS: Minimally Invasive Surgery

MISS: Minimally Invasive Spinal Surgery

MRI: Magnetic Resonance Imaging

PEEK: Polyetheretherketone

PLIF: Posterior Lumbar Interbody Fusion

POD: Physician-Owned Distributorship

SCS: Spinal Cord Stimulator

TDR: Total Disc Replacement

TLIF: Transforaminal Lumbar Interbody Fusion

UHWMPE: Ultra High Molecular Polyethylene

VBR: Vertebral Body Replacements

VCF: Vertebral Compression Fracture

XLIF: eXtreme Lateral Interbody Fusion



10.3 Sources

- Alphatec Spine (2012). Alphatec Spine Products, Available from: http://www.alphatecspine.com/products/index.asp. [Accessed August 17, 2012].
- Porucznik MA (2012). Physician-Owned Distributorships: A Problem or a Solution? American Academy
 of Orthopaedic Surgeons. Available from: http://www.aaos.org/news/aaosnow/feb12/advocacy1.asp.
 [Accessed on July 31, 2012].
- American Association of Neurological Surgeons (2009). Minimally Invasive Spine Surgery (MIS).
 Available from:
 - http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Minimally%20Invasive%20Spine%20Surgery%20MIS.aspx. [Accessed on August 17, 2012].
- B. Braun Medical Inc. (2012). Home, Products, Spine. Available from: http://www.bbraun.com/cps/rde/xchg/bbraun-com/hs.xsl/products.html?prid=PRID00004779. [Accessed August 17, 2012].
- Depuy Synthes (2012). North America/Products/Spine. Available from: http://www.synthes.com/sites/NA/Products/Spine/Pages/home.aspx. [Accessed August 17, 2012].
- Depuy Synthes (2012). ProDisc-C Total Disc Replacement. Available from:
 http://www.synthes.com/sites/NA/Products/Spine/Interbody_and_Vertebral_Body_Replacement_Systems/Pages/ProDisc-C-Total-Disc-Replacement.aspx. [Accessed August 27, 2012].
- Deyo RA (2010) New Study Demonstrates a Three-Fold Increase in Life-Threatening Complications With Complex Surgery. The Back Letter; 25(6): 66.
- Elder E.E (2007) Surgeon-Owned Device Companies: A Risky Proposition. Washington Legal Foundation. Available from: http://www.wlf.org/upload/1-26-07elder.pdf
- Epstein NE Hood DC (2011). "Unnecessary" spinal surgery: A prospective 1-year study of one surgeon's experience. Surgical Neurology International; 2: 83.
- FDA (2012). Inspections, Compliance, Enforcement, and Criminal Investigations. Enforcement Actions.
 Warning Letters. Lucero Medical, LLC 3/21/12. Available from:
 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm297333.htm. Accessed on
 [August 9, 2012]
- Garrido BJ, et al. (2011). Adjacent-level Cervical Ossification after Bryan Cervical Disc Arthroplasty Compared with Anterior Cervical Discectomy and Fusion. Journal of Bone and Joint Surgery; 93(13):1185-9.
- Globus Medical (2012). Our Products. Available from: http://www.globusmedical.com/products. [Accessed August 17, 2012].
- Hakkinen et al. (2007) Reoperations after first lumbar disc herniation surgery; a special interest on residives during a 5-year follow-up. BMC Musculoskeletal Disorders. 10.1186/1471-2474-8-2
- Himmelstein DU, et al. (2009) Medical Bankruptcy in the United States, 2007: results of a national study. The American Journal of Medicine; 122(8): 741-746.
- Krasoudakis A et al. (2010) Spinal Cord Stimulation for the treatment of Failed Back Surgery Syndrome.
 EANS Annual Meeting 2010. Available from: http://www.abstractserver.com/eans2010/eposter/documents/225.pdf.
- Lucio JC, et al. (2012). Economics of less invasive spinal surgery: an analysis of hospital cost differences between open and minimally invasive instrumented spinal fusion procedures during the perioperative period. Risk Management and Healthcare Policy; 5: 65-74.
- Martin BI, et al. (2007). Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures. Spine; 32: 382-387.
- Medtronic (2012). Patients, Cervical Herniated Discs, Prestige Cervical Disc, Available from: http://www.zimmer.com/z/ctl/op/global/action/1/id/9165/template/IN. [Accessed August 27, 2012].



- Nguyen TH, et al. (2011). Long-term outcomes of lumbar fusion among workers' compensation subjects: an historical cohort study. Spine; 36(4): 320-331.
- NuVasive (2012). Patient Solutions. Available from: http://www.nuvasive.com/patient-solutions. [Accessed August 17, 2012].
- Office of Inspector General (2011). 15.Levinson, DR, OIG Inspector General letter to Senators Hatch, Kohl, Grassley, Baucus, and Corker, September 13, 2011
- Orthofix International (2012). Products, Spine. Available from: http://intl.orthofix.com/index.php/site/product/spine. [Accessed August 17, 2012].
- Rajaee SS (2012). Spinal fusion in the United States: analysis of trends from 1998 to 2008. Spine; 37(1): 67-76.
- Röllinghoff M, et al. (2010). Mid-range outcomes in 64 consecutive cases of multilevel fusion for degenerative diseases of the lumbar spine. Orthopedic Review (Pavia); 2(1): e3.
- Senate Finance Committee Minority Staff (2011). Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight. Available from: http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c
- Smith JC (2011). Back Surgery: Too Many, Too Costly, Too Ineffective, Part 2. Dynamic Chiopractic; 29(08).
- Stryker (2012). Products, Spine. Available from: http://www.stryker.com/en-us/products/Spine/index.htm. [Accessed August 17, 2012].
- US Census (2012). Mid-year Population by Older Age Groups and Sex Custom Region China.
 Available from: http://www.census.gov/population/international/data/idb/region.php. [Accessed September 14, 2012]
- Van Dusen A (2008). America's Most Expensive Medical Conditions, Forbes, February 6, 2008
- Zimmer Spine (2012). Medical Professionals. Available from: http://www.zimmer.com/z/ctl/op/global/action/1/id/9165/template/null.htm. [Accessed August 17, 2012].
- Zimmer Spine, (2012), Medical Professionals, Dynesys Dynamic Stabilization System, Available from: http://www.zimmer.com/z/ctl/op/global/action/1/id/9165/template/IN. [Accessed August 27, 2012].



10.4 Research Methodology

GBI Research's dedicated research and analysis teams consist of experienced professionals in marketing and market research with consulting backgrounds in the medical devices industry and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Society of Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

10.4.1 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC filings.
- Industry trade journals, scientific journals and other technical literature.
- Internal and external proprietary databases.
- Relevant patent and regulatory databases.
- National government documents, statistical databases and market reports.
- Procedure registries.
- News articles, press releases and web-casts specific to the companies operating in the market.

10.4.2 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook.
- It helps in validating and strengthening the secondary research findings.
- It further develops the analysis team's expertise and market understanding.

Primary research involves email correspondence, telephone interviews and face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers.
- Hospital stores, laboratories, pharmacies, distributors and paramedics.
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical equipment markets.
- Key opinion leaders: physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.



10.4.3 Models

Where no hard data is available GBI Research uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross referenced with the following data types to produce estimates:

- Demographic data: population, split by segment.
- Macro-economic indicators: Gross Domestic Product, Inflation rate.
- Healthcare Indicators: health expenditure, physicians base, healthcare infrastructure and facilities.
- Selected epidemiological and procedure statistics.

Data is then cross-checked by the expert panel.

All data and assumptions relating to modeling are stored and are available to clients on request.

10.4.4 Forecasts

GBI Research uses proprietary forecast models. The following four factors are utilized in the forecast models:

- Historic growth rates.
- Macro indicators such as population trends and healthcare spending.
- Forecast epidemiological data.
- Qualitative trend information and assumptions.

Data is then cross-checked by the expert panel.

10.4.5 Expert Panels

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research's expert panel comprises marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies.

Historic data and forecasts are relayed to GBI Research's expert panel for feedback and adjusted in accordance with this feedback.



10.6 Disclaimer

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