Spinal Surgery Devices Market to 2018
New Entrants and Technological Advances to Intensify Competition in the Spinal Fusion Segment
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.
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.

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 Contents ................................................................................................................. 5
  1.1 List of Tables ..................................................................................................................... 8
  1.2 List of Figures .................................................................................................................... 10

2 Introduction ........................................................................................................................ 11

3 Spinal Surgery Devices - Overview ................................................................................... 12
  3.1 Spinal Fusion Devices ....................................................................................................... 12
  3.2 Spinal Non-Fusion Devices ............................................................................................... 12

4 Spinal Surgery Devices - Market Characterization ............................................................. 13
  4.1 Global Spinal Surgery Devices Market, Revenue ($m), 2004-2011 .................................... 13
  4.2 Global Spinal Surgery Devices Market, Revenue ($m), 2011-2018 ..................................... 14
  4.3 Global Spinal Surgery Devices Market, Key Company Share (%), 2011 ......................... 15
  4.4 Global Spinal Surgery Devices: Key Trends .................................................................... 16
    4.4.1 Physician-Owned Distributorship Models Experience a Decline in the Spinal Surgery Market
    ............................................................................................................................................. 16
    4.4.2 Competition Expected to Increase as Companies Capitalize on Technological Advances in the Spinal Fusion Market .............................................................. 17
  4.5 Global Spinal Surgery Devices: Market Dynamics ........................................................... 19
    4.5.1 Market Drivers ............................................................................................................ 19
    4.5.2 Market Restraints ....................................................................................................... 22

5 Global Spinal Surgery Devices Market - Segment Analysis and Forecasts ......................... 24
  5.1 Global Spinal Fusion Devices Market, Revenue ($m), 2004-2011 ...................................... 24
  5.2 Global Spinal Fusion Devices Market, Revenue ($m), 2011-2018 .................................... 25
  5.3 Global Spinal Fusion Devices: Market Dynamics .............................................................. 26
    5.3.1 Market Drivers ............................................................................................................ 26
    5.3.2 Market Restraints ....................................................................................................... 27
  5.4 Global Spinal Non-Fusion Devices Market, Revenue ($m), 2004-2011 ............................. 28
  5.5 Global Spinal Non-Fusion Devices Market, Revenue ($m), 2011-2018 ........................... 29
  5.6 Global Spinal Non-Fusion Devices: Market Dynamics ..................................................... 30
    5.6.1 Market Drivers ............................................................................................................ 30
    5.6.2 Market Restraints ....................................................................................................... 32

6 Global Spinal Surgery Devices Market - Country Analysis and Forecasts .......................... 34
  6.1 Spinal Surgery Devices Market: Cross-country Analysis ................................................ 34
  6.2 Historic and Forecast Revenue, By Country ..................................................................... 36
    6.2.1 Spinal Surgery Devices Market, US, Revenue ($m), 2004-2011 ................................. 36
    6.2.2 Spinal Surgery Devices Market, US, Revenue ($m), 2011-2018 .................................. 37
    6.2.3 Spinal Surgery Devices Market, Japan, Revenue ($m), 2004-2011 ............................. 38
    6.2.4 Spinal Surgery Devices Market, Japan, Revenue ($m), 2011-2018 ........................... 39
    6.2.5 Spinal Surgery Devices Market, Germany, Revenue ($m), 2004-2011 ......................... 40
    6.2.6 Spinal Surgery Devices Market, Germany, Revenue ($m), 2011-2018 ....................... 41
    6.2.7 Spinal Surgery Devices Market, China, Revenue ($m), 2004-2011 .............................. 42
    6.2.8 Spinal Surgery Devices Market, China, Revenue ($m), 2011-2018 ............................. 43
    6.2.9 Spinal Surgery Devices Market, UK, Revenue ($m), 2004-2011 .................................. 44
    6.2.10 Spinal Surgery Devices Market, UK, Revenue ($m), 2011-2018 ............................... 45
    6.2.11 Spinal Surgery Devices Market, Spain, Revenue ($m), 2004-2011 ............................ 46
    6.2.12 Spinal Surgery Devices Market, Spain, Revenue ($m), 2011-2018 ........................... 47
    6.2.13 Spinal Surgery Devices Market, France, Revenue ($m), 2004-2011 ........................... 48
    6.2.14 Spinal Surgery Devices Market, France, Revenue ($m), 2011-2018 .......................... 49
    6.2.15 Spinal Surgery Devices Market, Italy, Revenue ($m), 2004-2011 .............................. 50
    6.2.16 Spinal Surgery Devices Market, Italy, Revenue ($m), 2011-2018 .............................. 51
    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 Spinal Surgery Devices Market - Competitive Assessment ........................................60
7.1 Medtronic .........................................................................................................................61
7.1.1 Business Overview ........................................................................................................61
7.1.2 Products Marketed .........................................................................................................61
7.2 DePuy Synthes ..................................................................................................................62
7.2.1 Business Overview ........................................................................................................62
7.2.2 Products Marketed .........................................................................................................62
7.3 Stryker ..............................................................................................................................63
7.3.1 Business Overview ........................................................................................................63
7.3.2 Products Marketed .........................................................................................................63
7.4 NuVasive ..........................................................................................................................64
7.4.1 Business Overview ........................................................................................................64
7.4.2 Products Marketed .........................................................................................................64
7.5 Orthofix ............................................................................................................................65
7.5.1 Business Overview ........................................................................................................65
7.5.2 Products Marketed .........................................................................................................65
7.6 Zimmer Holdings ............................................................................................................66
7.6.1 Business Overview ........................................................................................................66
7.6.2 Products Marketed .........................................................................................................66
7.7 Globus Medical ................................................................................................................67
7.7.1 Business Overview ........................................................................................................67
7.7.2 Products Marketed .........................................................................................................67
7.8 Alphatec Holdings ..........................................................................................................68
7.8.1 Business Overview ........................................................................................................68
7.8.2 Products Marketed .........................................................................................................68
7.9 B. Braun Medical ............................................................................................................69
7.9.1 Business Overview ........................................................................................................69
7.9.2 Products Marketed .........................................................................................................69

8 Global Spinal Surgery Devices Market - Product Pipeline Analysis ..................................70
8.1 Spinal Fusion Devices: Product Pipeline .........................................................................71
8.1.1 Spinal Fusion Devices: Profiles of Key Pipeline Products ..........................................71
8.1.2 Spinal Fusion Devices: List of Pipeline Products .........................................................75
8.2 Spinal Non-Fusion Devices: Product Pipeline .................................................................78
8.2.1 Spinal Non-Fusion Devices: Profiles of Key Pipeline Products ....................................78
8.2.2 Spinal Non-Fusion Devices: List of Pipeline Products .................................................83

9 Global Spinal Surgery Devices Market - Consolidation Landscape ................................86
9.1 Spinal Surgery Devices Market: Number of Deals and Deal Value, 2007-2011 ...........86
9.2 Key Deals: 2007-2011 .....................................................................................................87
9.2.1 Globus Medical’s Acquisition of Facet Solutions .........................................................87
9.2.2 Alphatec Spine’s Acquisition of Scient’x Groupe .........................................................87
9.2.3 NuVasive’s Acquisition of Cervitech .........................................................................88
9.2.4 Zimmer Holdings’ Acquisition of Abbott Spine from Abbott Labs ...........................89
9.2.5 Regeneration Technologies’ Acquisition of Tutogen Medical ....................................90
9.2.6 Medtronic’s Acquisition of Kyphon ............................................................................91

10 Appendix .........................................................................................................................92
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1</td>
<td>Definitions</td>
<td>92</td>
</tr>
<tr>
<td>10.1.1</td>
<td>Spinal Surgery Devices</td>
<td>92</td>
</tr>
<tr>
<td>10.2</td>
<td>Acronyms</td>
<td>93</td>
</tr>
<tr>
<td>10.3</td>
<td>Sources</td>
<td>94</td>
</tr>
<tr>
<td>10.4</td>
<td>Research Methodology</td>
<td>96</td>
</tr>
<tr>
<td>10.4.1</td>
<td>Secondary Research</td>
<td>96</td>
</tr>
<tr>
<td>10.4.2</td>
<td>Primary Research</td>
<td>96</td>
</tr>
<tr>
<td>10.4.3</td>
<td>Models</td>
<td>97</td>
</tr>
<tr>
<td>10.4.4</td>
<td>Forecasts</td>
<td>97</td>
</tr>
<tr>
<td>10.4.5</td>
<td>Expert Panels</td>
<td>97</td>
</tr>
<tr>
<td>10.5</td>
<td>Contact Us</td>
<td>97</td>
</tr>
<tr>
<td>10.6</td>
<td>Disclaimer</td>
<td>98</td>
</tr>
</tbody>
</table>
1.1 List of Tables

Table 1: Global Spinal Surgery Devices Market, Revenue ($m), 2004-2011 ........................................13
Table 2: Global Spinal Fusion Devices Market, Revenue ($m), 2011-2018 ........................................14
Table 3: Global Spinal Non-Fusion Devices Market, Revenue ($m), 2011-2018 .............................15
Table 4: Global Spinal Surgery Market, Key Company Share ($m), 2011 .........................................16
Table 5: Global Spinal Fusion Devices Market, Minimally Invasive Spinal Fusion Techniques and Developing Companies .................................................................17
Table 6: Spinal Surgery Devices Market, Population Aged above 60, Top 12 Countries, 2010 .................21
Table 7: Global Spinal Fusion Devices Market, Revenue ($m), 2004-2011 .........................................24
Table 8: Global Spinal Fusion Devices Market, Revenue ($m), 2011-2018 .........................................25
Table 9: Global Spinal Non-Fusion Devices Market, Revenue ($m), 2004-2011 ..............................28
Table 10: Global Spinal Non-Fusion Devices Market, Revenue ($m), 2011-2018 ............................29
Table 11: Spinal Fusion Devices Market, Cross-country Analysis, Global, CAGR (%), 2004-2018 ..............30
Table 12: Spinal Fusion Devices Market, China, Revenue ($m), 2011-2018 ........................................31
Table 13: Spinal Fusion Devices Market, China, Revenue ($m), 2004-2011 ........................................34
Table 14: Spinal Fusion Devices Market, US, Revenue ($m), 2011-2018 ...........................................36
Table 15: Spinal Fusion Devices Market, Japan, Revenue ($m), 2011-2018 .......................................39
Table 16: Spinal Fusion Devices Market, Germany, Revenue ($m), 2011-2018 ...............................40
Table 17: Spinal Fusion Devices Market, France, Revenue ($m), 2011-2018 ....................................41
Table 18: Spinal Fusion Devices Market, Italy, Revenue ($m), 2011-2018 .........................................42
Table 19: Spinal Fusion Devices Market, Latin America, Revenue ($m), 2011-2018 .........................43
Table 20: Spinal Fusion Devices Market, Middle East, Revenue ($m), 2011-2018 ..........................44
Table 21: Spinal Fusion Devices Market, Africa, Revenue ($m), 2011-2018 ......................................45
Table 22: Spinal Fusion Devices Market, Australia, Revenue ($m), 2011-2018 .............................47
Table 23: Spinal Fusion Devices Market, Canada, Revenue ($m), 2011-2018 ...............................48
Table 24: Spinal Fusion Devices Market, India, Revenue ($m), 2011-2018 ......................................49
Table 25: Spinal Fusion Devices Market, Global, Revenue ($m), 2011-2018 ....................................50
Table 26: Spinal Fusion Devices Market, Global, Revenue ($m), 2004-2011 .....................................51
Table 27: Spinal Fusion Devices Market, Japan, Revenue ($m), 2004-2011 .....................................52
Table 28: Spinal Fusion Devices Market, US, Revenue ($m), 2004-2011 .........................................53
Table 29: Spinal Fusion Devices Market, Global, Revenue ($m), 2011-2018 ....................................54
Table 30: Spinal Fusion Devices Market, Global, Revenue ($m), 2004-2011 .....................................55
Table 31: Spinal Fusion Devices Market, Global, Revenue ($m), 2011-2018 ....................................56
Table 32: Spinal Fusion Devices Market, Global, Revenue ($m), 2004-2011 .....................................57
Table 33: Spinal Fusion Devices Market, Global, Revenue ($m), 2011-2018 ....................................58
Table 34: Spinal Fusion Devices Market, Global, Revenue ($m), 2004-2011 .....................................59
Table 35: Spinal Fusion Devices Market, Global, Revenue ($m), 2011-2018 ....................................60
Table 36: Spinal Fusion Devices Market, Global, Revenue ($m), 2004-2011 .....................................61
Table 37: Medtronic, Key Marketed Products, 2012 ........................................................................62
Table 38: DePuy Synthes, Key Marketed Products, 2012 ..............................................................63
Table 39: Stryker, Key Marketed Products, 2012 ..............................................................................64
Table 40: NuVasive, Key Marketed Products, 2012 ..........................................................................65
Table 41: Orthofix, Key Marketed Products, 2012 ............................................................................66
Table 42: Zimmer, Key Marketed Products, 2012 ............................................................................67
Table 43: Globus Medical, Key Marketed Products, 2012 .............................................................68
Table 44: Alphatec Medical, Key Marketed Products, 2012 ...........................................................69
Table 45: B. Braun Medical Inc., Key Marketed Products, 2012 ......................................................70
Table 46: CleanFUZE, Product Status, 2012 ....................................................................................71
Table 47: InterFuse Lateral System, Product Status, 2012 ..............................................................72
Table 48: C-Varlock, Product Status, 2012 .....................................................................................73
Table 49: OsseoScrew Spinal Fixation System, Product Status, 2012 ..............................................74
Table 50: XPED Expanding Pedicle Screw System, Product Status, 2012 ....................................75
Table 51: Pioneer QUANTUM Spinal Rodding System, Product Status, 2012 .............................76
Table 52: ACADIA Facet Replacement System, Product Status, 2012 ............................................77
Table 53: Barricaid ARD, Product Status, 2012 ..............................................................................78
Table 54: FLEXUS Interospinous Spacer, Product Status, 2012 .....................................................79
Table 55: IntelliRod System, Product Status, 2012 .......................................................................80
Table 56: Spinal Fusion Devices, Global Pipeline Products, 2012, Table 1 ........................................81
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
Table of Contents

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 ............................................ 14
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 .................................................................................................. 20
Figure 7: Global Spinal Fusion Devices Market, Revenue ($m), 2004-2011 .............................................. 24
Figure 8: Global Spinal Fusion Devices Market, Revenue ($m), 2011-2018 .............................................. 25
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 ($m), 2004-2011 ................................................. 36
Figure 14: Spinal Surgery Devices Market, US, Revenue ($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 ($m), 2004-2011 ........................................ 40
Figure 18: Spinal Surgery Devices Market, Germany, Revenue ($m), 2011-2018 ........................................ 41
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: Spinal Surgery Devices Market, UK, Revenue ($m), 2004-2011 ................................................. 44
Figure 22: Spinal Surgery Devices Market, UK, Revenue ($m), 2011-2018 ................................................. 45
Figure 23: Spinal Surgery Devices Market, Spain, Revenue ($m), 2004-2011 ............................................. 46
Figure 24: Spinal Surgery Devices Market, Spain, Revenue ($m), 2011-2018 ............................................. 47
Figure 25: Spinal Surgery Devices Market, France, Revenue ($m), 2004-2011 ........................................... 48
Figure 26: Spinal Surgery Devices Market, France, Revenue ($m), 2011-2018 ........................................... 49
Figure 27: Spinal Surgery Devices Market, Italy, Revenue ($m), 2004-2011 .............................................. 50
Figure 28: Spinal Surgery Devices Market, Italy, Revenue ($m), 2011-2018 .............................................. 51
Figure 29: Spinal Surgery Devices Market, Australia, Revenue ($m), 2004-2011 ....................................... 52
Figure 30: Spinal Surgery Devices Market, Australia, Revenue ($m), 2011-2018 ....................................... 53
Figure 31: Spinal Surgery Devices Market, Brazil, Revenue ($m), 2004-2011 ............................................. 54
Figure 32: Spinal Surgery Devices Market, Brazil, Revenue ($m), 2011-2018 ............................................. 55
Figure 33: Spinal Surgery Devices Market, Canada, Revenue ($m), 2004-2011 .......................................... 56
Figure 34: Spinal Surgery Devices Market, Canada, Revenue ($m), 2011-2018 .......................................... 57
Figure 35: Spinal Surgery Devices Market, India, Revenue ($m), 2004-2011 ............................................. 58
Figure 36: Spinal Surgery Devices Market, India, Revenue ($m), 2011-2018 ............................................. 59
Figure 37: Global Spinal Surgery, Competitive Assessment, 2011 ................................................................. 60
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.
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.

Figure 51: Spinal Surgery Devices Market, Product Pipeline Analysis, 2012

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%.

Source: GBI Research’s proprietary database [accessed on October 31, 2012]; primary research interviews with marketing managers and other industry experts
9 Global Spinal Surgery Devices Market - Consolidation Landscape

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

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 vertebra 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

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Artificial Disc Replacement</td>
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<tr>
<td>ALIF</td>
<td>Axial Lateral Interbody Fusion</td>
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<tr>
<td>ASD</td>
<td>Adjacent-Segment Degeneration</td>
</tr>
<tr>
<td>BMP-2</td>
<td>Bone Morphogenetic Protein-2</td>
</tr>
<tr>
<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
</tr>
<tr>
<td>CRDM</td>
<td>Cardiac Rhythm Disease Management</td>
</tr>
<tr>
<td>DDD</td>
<td>Degenerative Disc Disease</td>
</tr>
<tr>
<td>DLIF</td>
<td>Direct Lateral Interbody Fusion</td>
</tr>
<tr>
<td>FBSS</td>
<td>Failed Back Surgery Syndrome</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>HPAN</td>
<td>Hydrolyzate Polyacrylonitrile</td>
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<tr>
<td>IDE</td>
<td>Investigational Device Exemption</td>
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<tr>
<td>IPD</td>
<td>Interspinous Process Decompression</td>
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<tr>
<td>LADR</td>
<td>Lumbar Artificial Disc Replacement</td>
</tr>
<tr>
<td>LIF</td>
<td>Lateral Interbody Fusion</td>
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<tr>
<td>LSS</td>
<td>Lumbar Spinal Stenosis</td>
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<tr>
<td>MAS</td>
<td>Maximum Access Surgery</td>
</tr>
<tr>
<td>MIS</td>
<td>Minimally Invasive Surgery</td>
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<tr>
<td>MISS</td>
<td>Minimally Invasive Spinal Surgery</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>PEEK</td>
<td>Polyetheretherketone</td>
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<tr>
<td>PLIF</td>
<td>Posterior Lumbar Interbody Fusion</td>
</tr>
<tr>
<td>POD</td>
<td>Physician-Owned Distributorship</td>
</tr>
<tr>
<td>SCS</td>
<td>Spinal Cord Stimulator</td>
</tr>
<tr>
<td>TDR</td>
<td>Total Disc Replacement</td>
</tr>
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<td>Transforaminal Lumbar Interbody Fusion</td>
</tr>
<tr>
<td>UHWMPE</td>
<td>Ultra High Molecular Polyethylene</td>
</tr>
<tr>
<td>VBR</td>
<td>Vertebral Body Replacements</td>
</tr>
<tr>
<td>VCF</td>
<td>Vertebral Compression Fracture</td>
</tr>
<tr>
<td>XLIF</td>
<td>eXtreme Lateral Interbody Fusion</td>
</tr>
</tbody>
</table>
10.3 Sources


- 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


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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