RESEARCH METHODOLOGY

1) Secondary Research: Information was collected from a number of public and paid data sources. Public sources involved Government websites, publications from different countries, company annual reports, white papers and research publications by recognized industry experts. Paid data sources include authentic industry databases.

2) Primary Research: After collecting data from secondary sources, primary interviews were conducted with stakeholders at different points of the feed value chain like manufacturers, distributors, ingredient suppliers and key opinion leaders of the industry. Primary research is used both to validate the data points obtained from secondary research and to fill any gaps in data.

3) Market Analysis: The market analysis phase involves analyzing the collected data, market breakdowns and forecasting. Macroeconomic indicators and bottom-up and top-down approaches are used to arrive at a complete set of data points that give way to valuable qualitative and quantitative insights. Each data point is verified by the process of data triangulation to validate the numbers and arrive at a close estimate.

4) Expert Validation: The market analysis data is verified and validated by a number of experts, both in-house and external.

5) Report Writing: After the data is curated through the process, our analysts begin to write the report. Garnering insights from data and forecasts, insights are drawn to visualize the entire business ecosystem in a single report.
1. INTRODUCTION

1.1 MARKET DEFINITION

Spinal surgical device market is a very significant and money-spinning sub section of orthopedic industry. Spine surgery is traditionally done as "open surgery," wherein a long incision allows the surgeon to access the spine anatomy. In the recent years, a minimally invasive surgical device technique has received increasing attention as it does not involve a long incision and hence causes minimal damage to the muscles around the spine. This results in lesser post-operative pain and faster recovery.

Spinal surgeries can be classified as:

- ALIF (Anterior Lumbar Interbody Fusion) — for removal of a complete intervertebral disc.
- Anterior Cervical Discectomy — to remove selected discs.
- Bone Grafting — to place bone into an area of the spine in order to get solid bone healing (spinal fusion).
- Discectomy — to remove a part or all of an intervertebral disc from the spine.
- Spinal Decompression
- Spinal Fusion
- Spinal Instrumentation
- Spinal Osteotomy
- Thoracoscopic Release
- TLIF

North America is estimated to contribute to the largest market share of the global Spinal implants & surgical device market. Increasing technological awareness, population and sedentary lifestyles is bound to increase the market for spinal surgical device all around the world. Motion-preservation techniques in spinal non-fusion procedures are predicted to be the next big thing in spinal surgery, and have seen enhanced adoption rates over the last few years.
2. EXECUTIVE SUMMARY

Spinal surgery devices are used in the treatment of spine-related disorders, including back pain, degenerative disc disease, trauma, and deformities. This market is being driven by an aging population resulting in a greater number of age-related spinal pathologies, such as degenerative disc disease, herniated discs, and spinal tumors. Medical companies bend over backwards to meet need for advanced spinal surgery devices and the market for spinal surgery devices is being driven forward, as patients are offered safer, faster and effective method of treatment.

The North America Spinal surgery devices market consists of fusion, non-fusion, spinal decompression, VCFs treatment products. The market for spinal surgery devices is being driven by many factors, which includes patients offered safer, more reliable surgery that will preserve natural movement and prevent degeneration of the spine. Innovative techniques can now maintain spinal mobility while treating spinal degeneration and a number of manufacturers have developed motion-preserving devices to exploit this growing trend. Moreover, techniques like Minimally Invasive Spinal Surgery (MISS) is used to implant these devices and surgeons are finding a number of clinical benefits of this.

In this report, we have discussed the major drivers and restraints of the Spinal Surgery device market, followed by opportunities and challenges. The report also reviews the competitive landscape with major acquisitions and mergers in the last three years and a detailed analysis of the pipeline products and the profile of major companies in each category. Key geographies covered include the US, Canada and Mexico.
3. MARKET OVERVIEW

3.1 MARKET DRIVERS

Increasing incidence of spinal disorders

Spine-related disorders are among the most frequently encountered problems in clinical medicine. Low back pain (LBP) alone affects up to 80% of the population at some point in life, and in United States it affects 1% to 2% of the adult population. The estimated total cost of direct medical expenditures in the United States for spine care in 2010 was more than $96 billion, and the use and costs of spine care have been increasing at an alarming rate in recent years.

Pain in neck and back are the major manifestations covered under spinal disorders. The 2010 Global Burden of Disease Study estimated that low back pain is among the top 10 diseases and injuries that account for the highest number of DALYs worldwide. In the United States, an estimated 149 million work days are lost every year because of low back pain, with total costs estimated to be US$ 100 to 200 billion.

Surgical rates for spinal stenosis varied almost five-fold among U.S. states. Overall rate of lumbar surgery among Medicare beneficiaries continued to rise in the recent years. Approximately 122,316 lumbar fusions for degenerative conditions were performed in 2001 and there has been a significant increase in fusions in 2013.

Increased 3-D Image Guided Spine Surgery

3-D image guided spine surgery is expected to drive the growth of spinal surgery devices market in the future. The technology provides 3-D images of the surgical devices used in the anatomy and enables the surgeon to make minute changes thereby increasing accuracy. The surgeon can precisely locate the entry point and the trajectory for the position of spinal implant. This reduces the risk of injury to the nerves and nerve roots significantly and increases the probability of the desired outcome. In the December 2008 online edition of the Journal of
Neurosurgery, Spine 3D image-guided technology to place screws in the spine for spinal fusion procedures was published. The surgeons implanted 1084 screws in 220 patients and reported a nerve injury rate of less than one percent. The rate of misplacement of the screws was also less than one percent. This when compared to a reported nerve injury rate of up to 8 percent and a misplacement rate of up to 55 percent using standard technology is a milestone. The major benefits associated are reduction in operating time, increases efficacy of the procedure, reduces downtime, minimizes radiation exposure to x-rays and ensures patient safety.

**Minimally Invasive Lateral Interbody Fusion**

Minimally invasive lateral interbody fusion is expected to drive the growth of the spinal surgery devices market in the near future. Lateral interbody fusion is a minimally invasive alternative for traditional lumbar spinal fusion. In traditional lumbar spinal fusion the surgeon reaches the back through an incision in the abdomen. In the lateral interbody fusion the surgeon reaches the back through an incision in the side of the body by use of special tools and techniques. Approaching the spine through the abdomen is associated with a lot of drawbacks. This can lead to higher risk of injury to the nerves, blood vessels and other organs in the body and prolong the recovery time of the patient. Lateral approach provides an alternate entry where the surgeon has to encounter far fewer structures and tissues. Increased patient demand for minimally Invasive fusion methods will drive Spinal Surgical device market.

**Emerging Techniques**

There are several emerging interventional spine procedures. Intradiscal electrothermal therapy (IDET) procedure was developed and introduced in the 1990s as a less invasive alternative to fusion for discogenic back pain. There was a great deal of enthusiasm for this procedure based on early studies, and its use increased dramatically in the 1990s and early 2000s. Emerging surgical techniques in the market for spinal disorders is also a driving factor for the growth of the market. For example, the laser techniques can be used for patients with degenerative disc disease as well as other spinal disorders. Major techniques being implemented in the market are Stem cells for lumbar fusions and Pedicle screw alternative.
4. NORTH AMERICAN SPINAL SURGERY MARKET SEGMENTATION

4.1 SPINAL DECOMPRESSION

4.1.1 Corpectomy

Anterior cervical corpectomy and fusion (ACCF) is performed for patients with symptomatic, progressive cervical spinal stenosis and myelopathy. It is performed to remove the large, arthritic osteophytes (bone spurs) that are compressing the spinal cord and spinal nerves. However, in order to do so generally involves removing nearly the entire vertebral body and disc, which must be replaced with a piece of bone graft and mended (fused) together to maintain stability.

Technically, a corpectomy is a more difficult spine surgery to perform. Similar to a discectomy, the risks and possible complications of this surgery for cervical spinal stenosis include:

- Nerve root damage
- Damage to the spinal cord
- Bleeding
- Infection
- Graft dislodgment
- Damage to the trachea/esophagus
- Continued pain.

However, a corpectomy is a more extensive procedure than a discectomy, so the risks are statistically greater, especially with respect to neurologic issues, bone grafting and bleeding.

The risk that spine surgeons worry about the most is compromise of the spinal cord that can lead to complete or partial quadriplegia. Bear in mind that corpectomy surgeries are most often undertaken in circumstances of significant spinal cord problems, which place the cord at greater risk for problems during surgery, independent of the skill and finesse with which the procedure is performed.
Nearly 600000 spinal procedures were performed in the United States last year of which close to 13800 procedures were for Corpectomy. The average cost per procedure is about USD 8000 bringing the market size to be an estimated $110 million.

Table 1: North America Market for Corpectomy ($ Billions)

<table>
<thead>
<tr>
<th>Country</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2020</th>
<th>CAGR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>0.096</td>
<td>0.103</td>
<td>0.110</td>
<td>0.152</td>
<td>5.54</td>
</tr>
<tr>
<td>CANADA</td>
<td>0.038</td>
<td>0.041</td>
<td>0.043</td>
<td>0.058</td>
<td>5.11</td>
</tr>
</tbody>
</table>

Source: Mordor Intelligence Analysis
4.5 NON FUSION DEVICES

The Non-fusion spinal device are devices made collaboratively by engineers and medical practitioners creating devices that can be implanted without fusion in human body which helps to retain flexibility and movement of patients post-surgery. Although some nonfusion devices have been available on the US market for some time, their adoption has been somewhat limited to this point. A dearth of clinical data supporting the technology has resulted in many surgeons continuing to perform the procedure they are most comfortable with; namely, spinal fusion.

The introduction of new devices, such as nuclear disc prostheses, annulus repair devices and facet arthroplasty devices has also helped the market to expand due to easier acceptance of these by doctors and patients alike as compared to the invasive fusion devices.

North America contributes the largest market share as the degenerative disc disease affects almost 50% of the U.S. population above age 40 years. In addition, increasing prevalence of obesity in North American region also drives the growth of this market. But the Non fusion device market is still a long way behind the fusion market with it taking major market share.

Figure 8: Distribution of Fusion and non Fusion Device Market

Source: Mordor Intelligence analysis
4.6 MARKET SEGMENTATION BY COUNTRY

Canada
In Canada there are 1298 per million spine related cases where surgery of some sort is required. Here again the fusion market overtakes the non fusion device market. The Canadian market size is one fourth that of the US but is expanding with new technologies and better understanding of these technologies. The Canadian Market is expected to grow by a CAGR of 9.93% with the market size estimate to be close to $4 billion by 2020.

Figure 14: Market share of various procedures in Canada (2012)

Figure 15: Canada Spine Surgery Market ($ billions)
6. COMPANY PROFILES

6.1 GLOBUS MEDICAL, INC.

INTRODUCTION
Globus Medical, Inc. is a leading musculoskeletal implant manufacturer and is driving significant technological advancements across a complete suite of spinal products. Founded in 2003, Globus’ single-minded focus on advancing spinal surgery has made it the fastest growing company in the history of orthopedics. Globus is driven to utilize superior engineering and technology to achieve pain free, active lives for all patients with spinal disorders.

FINANCIALS

Globus Medical generated revenue of $434 million for the year 2013. This was a 12.27% increase in total revenue compared to the year 2012 where the revenue generated was as high as $385 million.

PRODUCTS & SERVICES

Globus Medical, Inc. offers approximately 120 products that address an array of spinal pathologies, anatomies, and surgical approaches. The company’s fusion products are used in cervical, thoracolumbar, sacral, and interbody/corpectomy fusion procedures to treat degenerative, deformity, tumor, and trauma conditions. Its disruptive technology products provide material improvements to fusion procedures, such as minimally invasive surgical techniques, as well as new treatment alternatives, which include motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous process spacer products, and advanced biomaterials technologies; and interventional pain management solutions, including treatments for vertebral compression fractures.
- **REVERE® ADDITION® Sacroiliac System**: The REVERE® ADDITION® Sacroiliac System is an adjunct to the REVERE® Stabilization System, providing a comprehensive set of implants for addressing complex cases.

- **SI-LOK®**: The SI-LOK® Sacroiliac Fixation System is a comprehensive set of hydroxyapatite (HA) coated screws, cannulated drill bits and wires specifically designed for a lateral approach to the sacroiliac (SI) joint.

- **REVOLVE® Low-Profile**: REVOLVE®, the most streamlined minimally invasive pedicle screw system on the market, is now available in a low-profile system offering.

- **InterContinental®**: InterContinental® Plate-Spacer is the next generation system in minimally invasive lateral fixation. The plate and spacer are fully contained within the disc space, minimizing disruption to patient anatomy. The optimized screw design compressively loads the graft to help promote fusion. The system offers a wide variety of footprints in order to meet different patient anatomy and to ensure optimal endplate contact.

- **CALIBER®-L**: CALIBER®-L is an expandable lateral lumbar fusion device designed to streamline insertion and optimize fit. Insertion of CALIBER®-L is performed at a contracted height to ease insertion. Controlled distraction is designed to maximize indirect decompression through disc height restoration. Continuous expansion resists migration by optimizing fit.

- **REVERE® Anterior Integrated Staple System (RAISS)**: REVERE® Anterior Integrated Staple System (RAISS) is a single-rod system that is ideal for multi-level anterior constructs to treat deformity, trauma and tumor cases. The design of the integrated staple allows for optimal placement on the vertebral body and intra-operative adaptability.

- **REVERE® Variable Cross Connector**: The REVERE® Variable Cross Connectors are slim, low profile connectors to enhance construct stability that allow angular and medial-lateral adjustments for a secure fit.

- **SP-Fix®**: SP-Fix® is a spinous process fixation device designed to provide structural stability, indirect decompression and immobilization of the spinous processes of adjacent vertebrae. SP-Fix® is implanted using a minimally invasive approach and preserves the supraspinous ligament. SP-Fix® offers surgeons an easy-to-use system that helps preserve patient anatomy. SP-Fix® is not a stand-alone device and requires additional fixation.
- **REVERE® Deformity Vertebral Derotation Instruments**: The REVERE® Deformity Vertebral Derotation Instruments aid in deformity correction maneuvers. Designed to be simple and stable, these instruments firmly interface with the screw heads and may be linked together with ease to perform axial derotation. This coupling feature allows for en bloc vertebral derotation which distributes the forces over multiple vertebral levels. The instruments are designed with full reduction capabilities and are cannulated to allow for introduction of locking caps and final tightening instruments.

- **FORTIFY®I**: The FORTIFY®I Corpectomy Spacer is designed to provide anterior column support and help prevent implant dislodgement. The spacer has integrated titanium screws for additional stabilization between the vertebral bodies and the spacer. The implants are available in a wide range of footprints, heights, lordotic/kyphotic angles in PEEK or titanium. Maximized expansion ranges and modular endplates allow surgeons to customize each implant to achieve the best possible fit for their patient.

- **TRIUMPH®**: The TRIUMPH® Lumbar Disc is a first-of-its-kind disc replacement device that is inserted through a posterolateral approach and is uniquely designed to permit a physiologic range of motion in all planes, regardless of insertion angle.

- **MARS™3V**: MARS™3V is a versatile and variable vision minimal access retractor system for unprecedented control of tissue retraction in a lumbar interbody fusion procedure.

- **GATEWAY®**: GATEWAY® is a low-profile lateral thoracolumbar plate system that combines the simplicity of a plate with the versatility of a rod system. Its “open-door” capability, combined with large graft windows, allows for total access to the corpectomy site.

- **CREO® Threaded**: The CREO® Threaded thoracolumbar stabilization system enhances efficiency and ease of use by providing a complete array of implant options for treating complex spinal pathologies with one system. The system displays a competitively low profile design and optimizes efficiency and visibility at the operative site with more intuitive and ergonomic instruments. Its design and development was inspired by creative innovation and product evolution through years of experience and surgical expertise.

- **SECURE®-C**: The SECURE®-C Cervical Artificial Disc is a motion-sparing technology designed as an alternative to fusion. Through its unique selectively constrained design, SECURE®-C is designed to allow up to ±15º motion in flexion-extension and up to ±10º motion in lateral bending. The design is intended to allow unlimited axial rotation and to permit sagittal plane translation of ±1.25mm. Clinical study data
demonstrate statistical superiority of SECURE®-C ACDF in terms of overall success, subsequent surgery, and patient satisfaction at 24 months postoperative.

- **FORGE™**: FORGE™ Cervical Allograft Spacer is a corticocancellous spacer designed to provide a natural option for anterior cervical fusion. This spacer is available in multiple sagittal profiles and heights to accommodate varying patient anatomy and optimize fit. Included in the FORGE™ system are innovative instruments designed to streamline the procedure.

- **ASSURE®-X**: ASSURE®-X combines the proven success of a low-profile anterior cervical plate with audible, tactile, and visual screw locking. The pre-assembled screws are quickly inserted and securely locked using one instrument.