U.S. Market for Minimally Invasive Spinal Implants

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iDATA_USMIS15_RPT

Published in December 2014

By

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U.S. MINIMALLY INVASIVE SPINAL IMPLANT MARKET OVERVIEW

3.1 Introduction

The spinal implant market is considered by many to be the most exciting and controversial segment of the orthopedics industry. This market has traditionally been a segment of the orthopedics market, but due to rapid growth and a large market size, many manufacturers view spine as a key business division separate from traditional orthopedics.

3.1.1 Spinous Process Fixation

Both plating systems as well as rod and screw systems used in traditional fusion procedures add bulk along the lateral aspect of the spine, which limits access to the pars and transverse processes of the spinal column. This complicates the removal of membranes and the placement of bone graft. As a result of the

limitations of plate and rod systems, there was a need for spinal stabilization devices that did not add bulk to the lateral aspect of the spine and did not limit access to the pars and transverse processes.

3.1.2 Facet Fixation

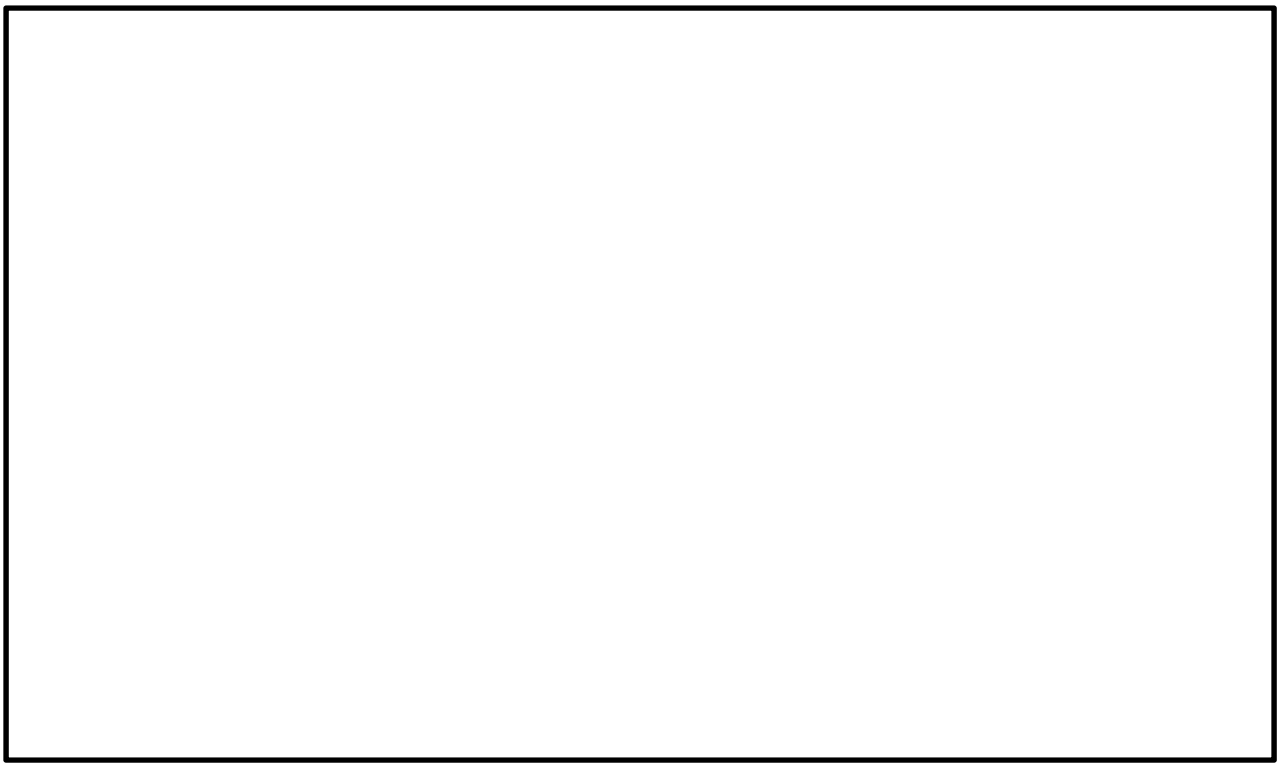
Percutaneous minimally invasive surgery (MIS) is the least invasive of all MIS procedures. These procedures are performed using small, needle-like, tubular instruments. The tubes act as a pathway for the insertion of screws or rods. All percutaneous systems use cannulated screws, which have a central cavity by which they are fed along a guidewire in the tube, allowing accurate implantation without directly viewing the surgical site.

3.1.3 Minimally Invasive Interbody Fusion

Interbody (IB) devices are designed to replace the intervertebral discs of the spine, which enhances stability in the region and promotes fusion between the two adjacent vertebral bodies. These devices are threaded, allowing them to be used in conjunction with bone graft material. Over time, the packed graft is gradually replaced by natural bone, forming a solid piece. IB fusion procedures typically add a posterior fixation device to the associated level. These procedures are often referred to as 360° fusions, as surgeons will implant interbody devices from an anterior approach and flip the patient over to implant a posterior pedicle screw device. This combination increases the fusion success rate over an interbody fusion device implantation alone.

3.1.3.1 Minimally Invasive Transforaminal Lumbar Interbody Fusion

Transforaminal lumbar interbody fusion (TLIF) devices are implanted posterolaterally, or from the side. This approach avoids the exposure of nerve roots and posterior ligaments and is gaining popularity because it is less invasive, with fewer complications than PLIF procedures.

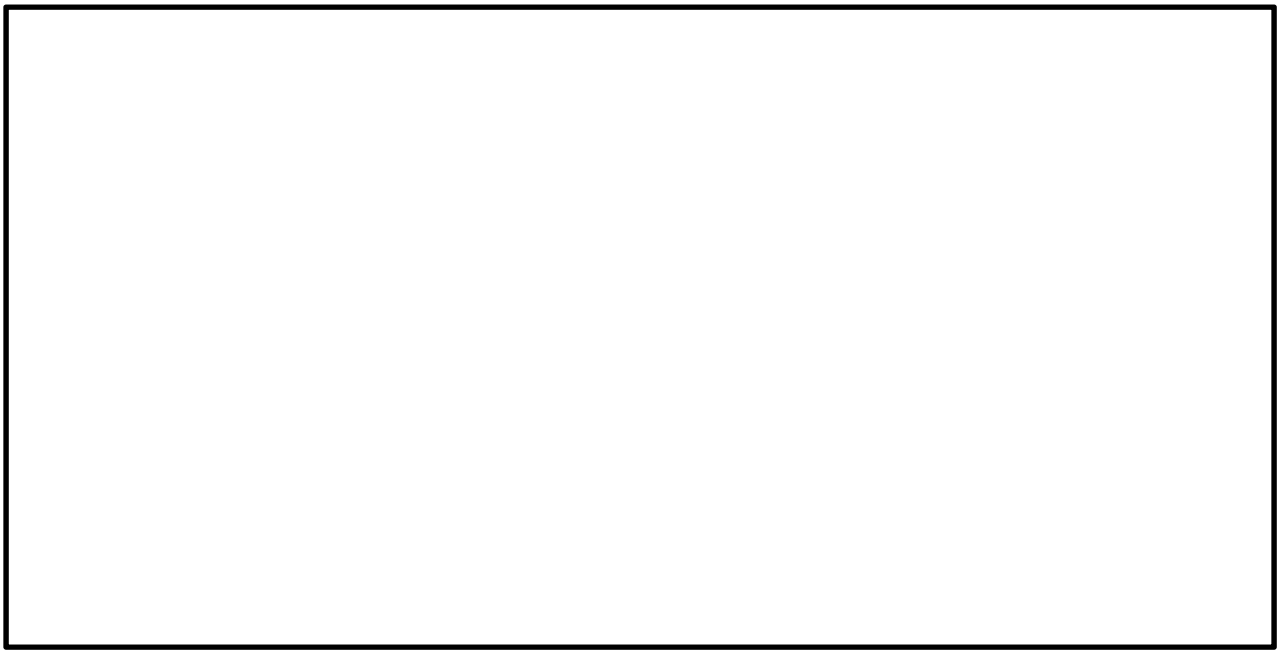


3.1.3.2 Minimally Invasive Posterior Lumbar Interbody Fusion

Minimally invasive posterior lumbar interbody fusion (MIPLIF) is a minimally invasive surgical technique that is performed in patients with lower back and radicular pain caused by degenerative disc disease (DDD), spondylolisthesis or disc herniation. This procedure typically takes about three hours and is performed from the back (posterior) with the patient on his or her stomach.

3.1.3.3 Lateral Lumbar Interbody Fusion

A number of newer techniques utilize a lateral approach in order to reach the spine. In 2014, more than ten lateral lumbar interbody fusion (LLIF) systems were available on the U.S. market, including NuVasive's popular *XLIF*®, Medtronic's *DLIF*® and Alphatec Spine's *GLIF*®.



3.1.4 Minimally Invasive Surgery (MIS) Pedicle Screws

Pedicle screws provide a means of stabilizing a spinal level during a fusion procedure. The screws do not fixate the levels, but act as firm anchor points that can then be connected with a rod. Pedicle screws can be placed at two or more consecutive spine levels; a short rod is subsequently implanted in order to connect the screws. The screw and rod construct prevents motion at the levels that are being fused.

3.1.4.1 Percutaneous MIS Systems

3.1.4.2 Retractor-Based MIS systems

3.1.5 MIS Sacroiliac Joint Fusion

Sacroiliac (SI) joint fusion is the fusion of the SI joint, which is found between the sacrum and iliac bones in the pelvic area. Fusion of this joint is required when a patient is suffering from SI joint dysfunction (SIJD), which studies have shown to be responsible for up to X% of lower back pain cases. However, growth of this market has been limited due to controversial diagnosis methods and a lack of effective treatments with positive long-term clinical data.

3.2 Market Overview

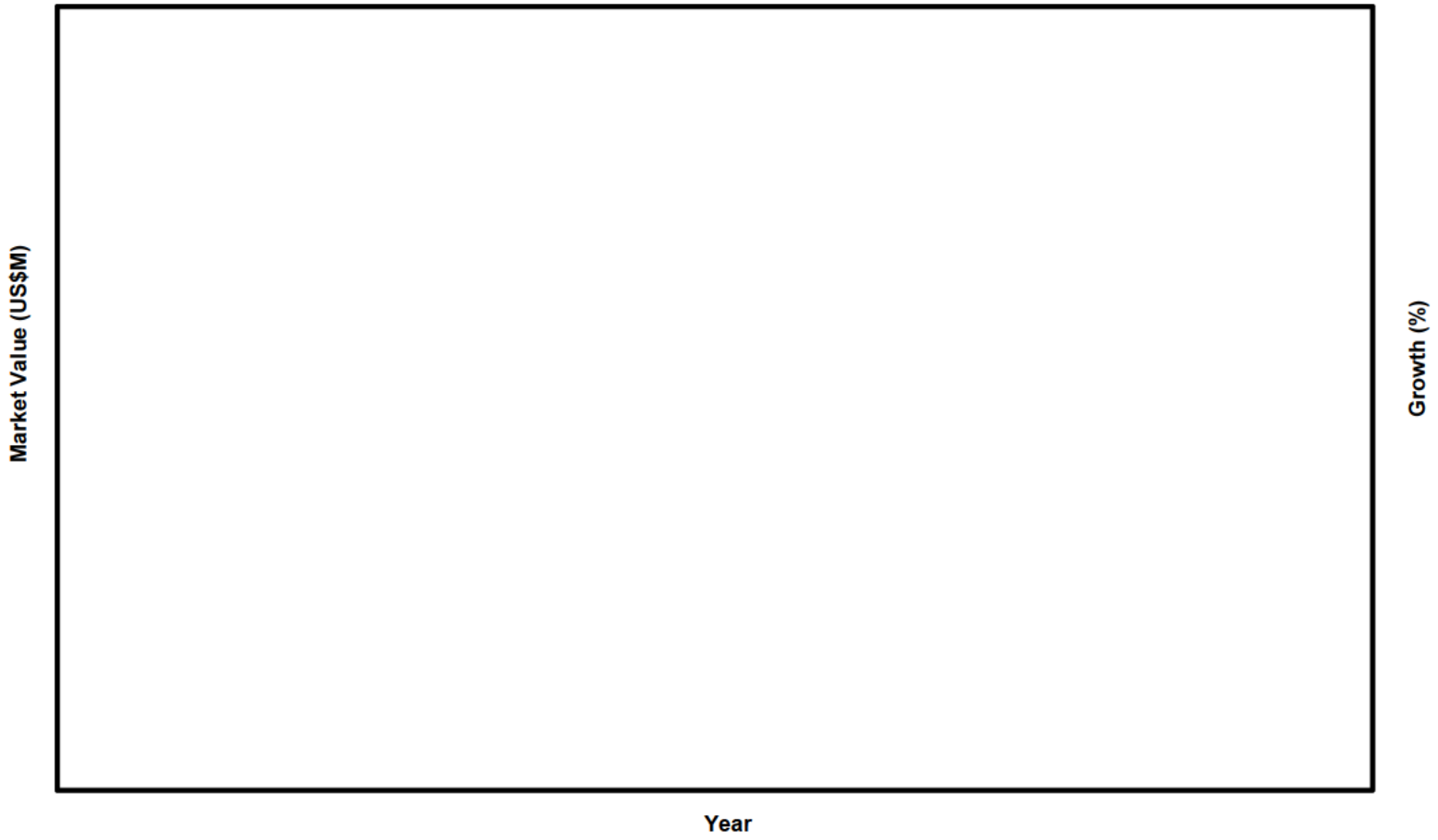
In 2014, the U.S. minimally invasive spinal implant market approached $X, an increase of X% over the previous year. The total market is expected to maintain a strong growth rate through 2017, until market saturation in certain MIS segments begins to slow the growth of the total market.

Figure 3-1: Total Minimally Invasive Spinal Implant Market, U.S., 2011 – 2021 (US$M)

Year	Total Market Value	Growth (%)

Source: iData Research Inc.

Chart 3-1: Total Minimally Invasive Spinal Implant Market, U.S., 2011 – 2021 (US$M)



Source: iData Research Inc.

3.3 Market by Segment

In 2014, the U.S. minimally invasive spinal implant market approached $X, an increase of X% over the previous year. The market consists of five segments: spinous process fixation, facet fixation, MIS interbody fusion, MIS pedicle screws and MIS sacroiliac (SI) joint fusion. The MIS interbody fusion market represented the largest segment in 2014, with a value in excess of $X. The second largest segment in 2014 was the MIS pedicle screw market, which was valued at $X, followed by facet fixation over $X, spinous process fixation at $X and finally MIS SI joint fusion just below $X.

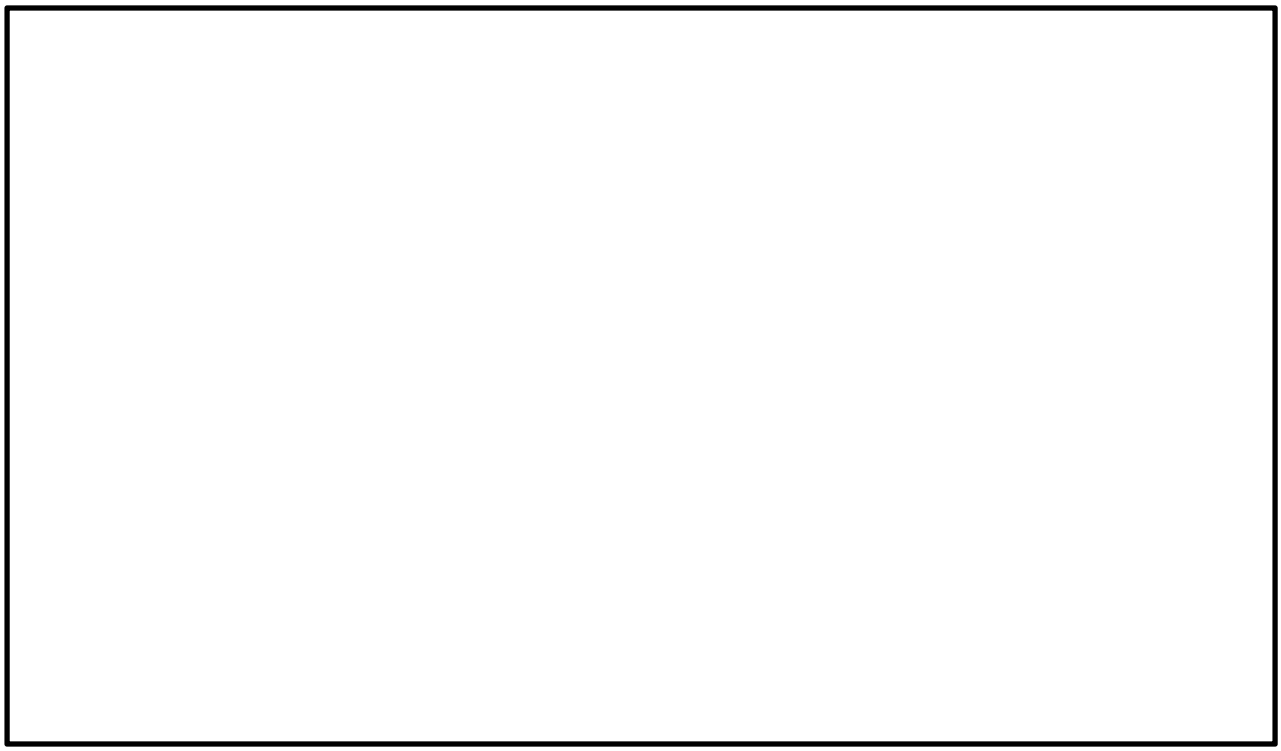
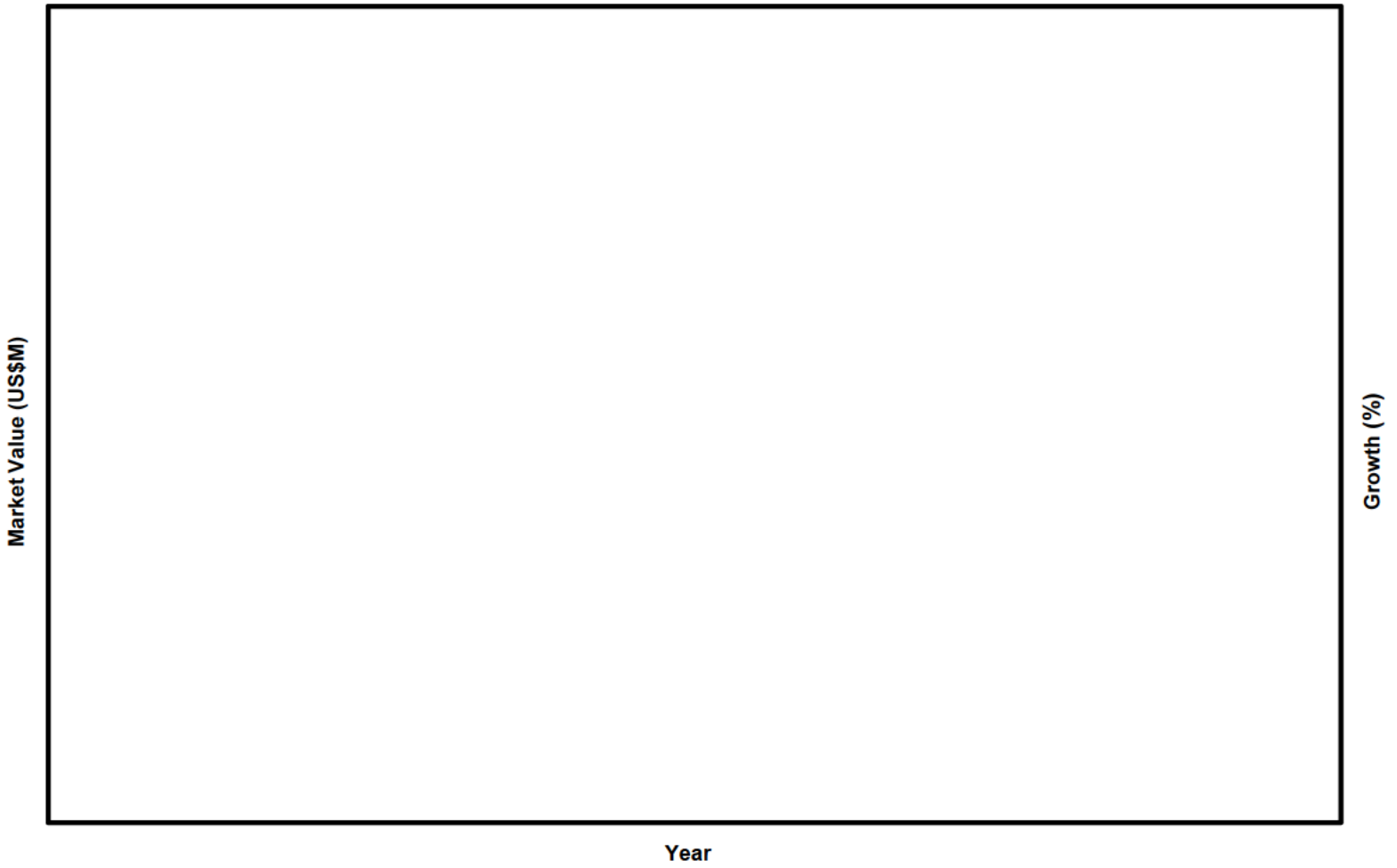


Figure 3-2: Minimally Invasive Spinal Implant Market by Segment, U.S., 2011 – 2021 (US$M)

Year	Spinous Process Fixation Market	Facet Fixation Market	MIS Interbody Fusion Market	MIS Pedicle Screw Market	MIS Sacroiliac Joint Fusion Market	Total Market Value	Growth (%)

Source: iData Research Inc.

Chart 3-2: Minimally Invasive Spinal Implant Market by Segment, U.S., 2011 – 2021



Source: iData Research Inc.

Chart 3-3: Minimally Invasive Spinal Implant Market Breakdown, U.S., 2014

Source: iData Research Inc.

Chart 3-4: Minimally Invasive Spinal Implant Market Breakdown, U.S., 2021

Source: iData Research Inc.

3.4 Trend Analysis by Segment

The fastest growing segment of the minimally invasive spinal implant market in 2014 was represented by spinous process fixation, which increased by X% over 2013. After emerging in 2005, this segment's growth has slowed down significantly in 2014 due to recent reimbursement changes that have affected almost half of the U.S. population. The segment will continue to be driven by the entrance of new competitors in the market, along with the growing acceptance of minimally invasive procedures among surgeons.

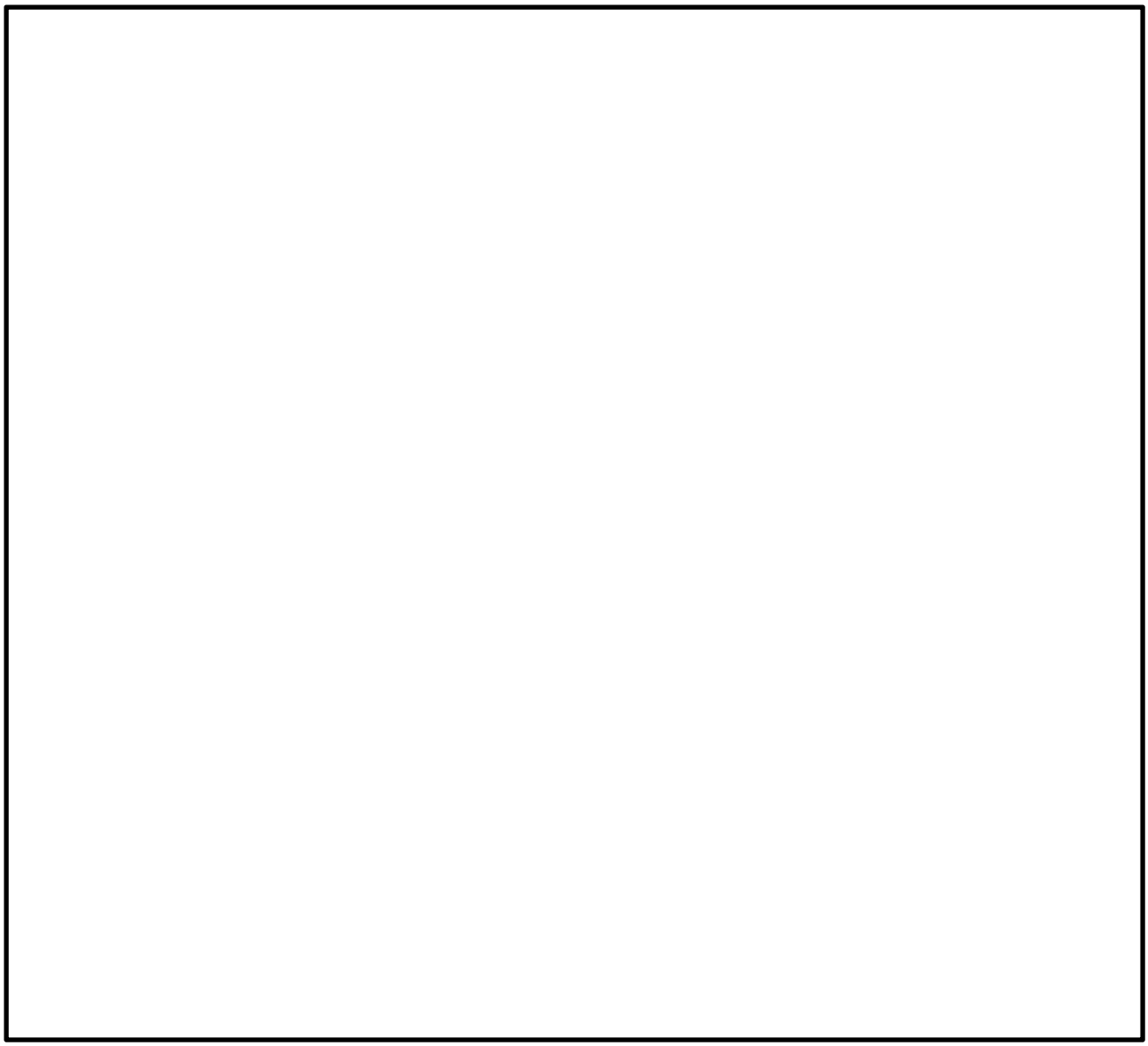
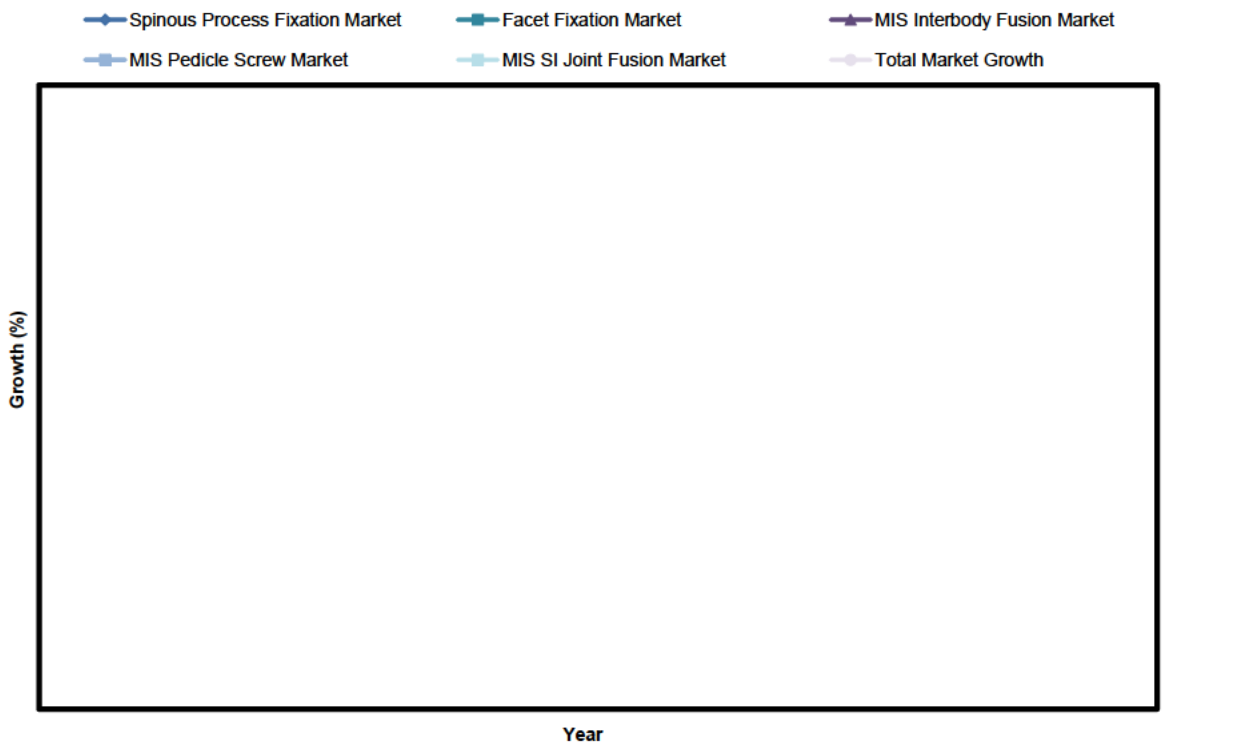


Figure 3-3: Minimally Invasive Spinal Implant Market Growth by Segment, U.S., 2011 – 2021

Year	Spinous Process Fixation Market	Facet Fixation Market	MIS Interbody Fusion Market	MIS Pedicle Screw Market	MIS Sacroiliac Joint Fusion Market	Total Market Growth

Source: iData Research Inc.

Chart 3-5: Minimally Invasive Spinal Implant Market Growth by Segment, U.S., 2011 – 2021



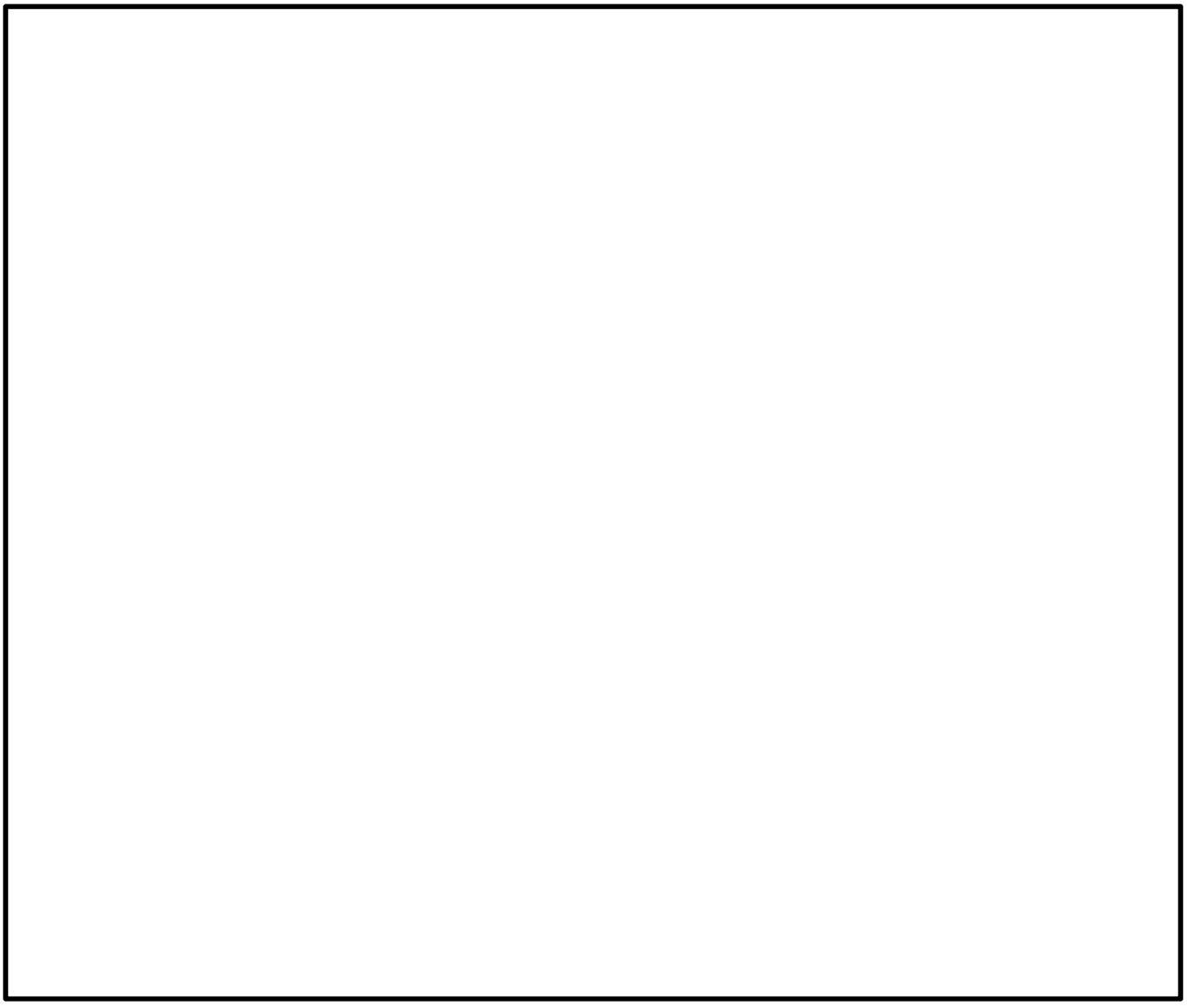
Source: iData Research Inc.

3.5 Drivers and Limiters

3.5.1 Market Drivers

Increase in Key Demographics

In 2014, the fastest growing population segment in the U.S. comprised those over the age of 65. This group represents the aging baby boomer generation. The majority of spinal fusions are performed to treat degenerative diseases that are often associated with age. The growing elderly population will increase the number of annual fusion procedures performed.



3.5.2 Market Limiters

Motion Preservation

Because MIS fusion is a segment within the total fusion market, factors that limit the growth of the total spinal fusion market will limit the MIS fusion market, including motion preservation devices. These devices offer an alternative to fusion that allows the preservation of motion in the indicated spinal segment. As more motion preservation devices, such as facet arthroplasty and nucleus replacement, emerge onto the U.S. market, the growth of the spinal fusion market will be increasingly limited by these devices. Although the MIS market may continue to grow within the total fusion market, it will eventually be limited by the general stagnation of spinal fusion that is expected over the forecast period as the market is cannibalized by motion preservation devices.

Figure 3-4: Drivers and Limiters, Minimally Invasive Spinal Implant Market, U.S., 2014

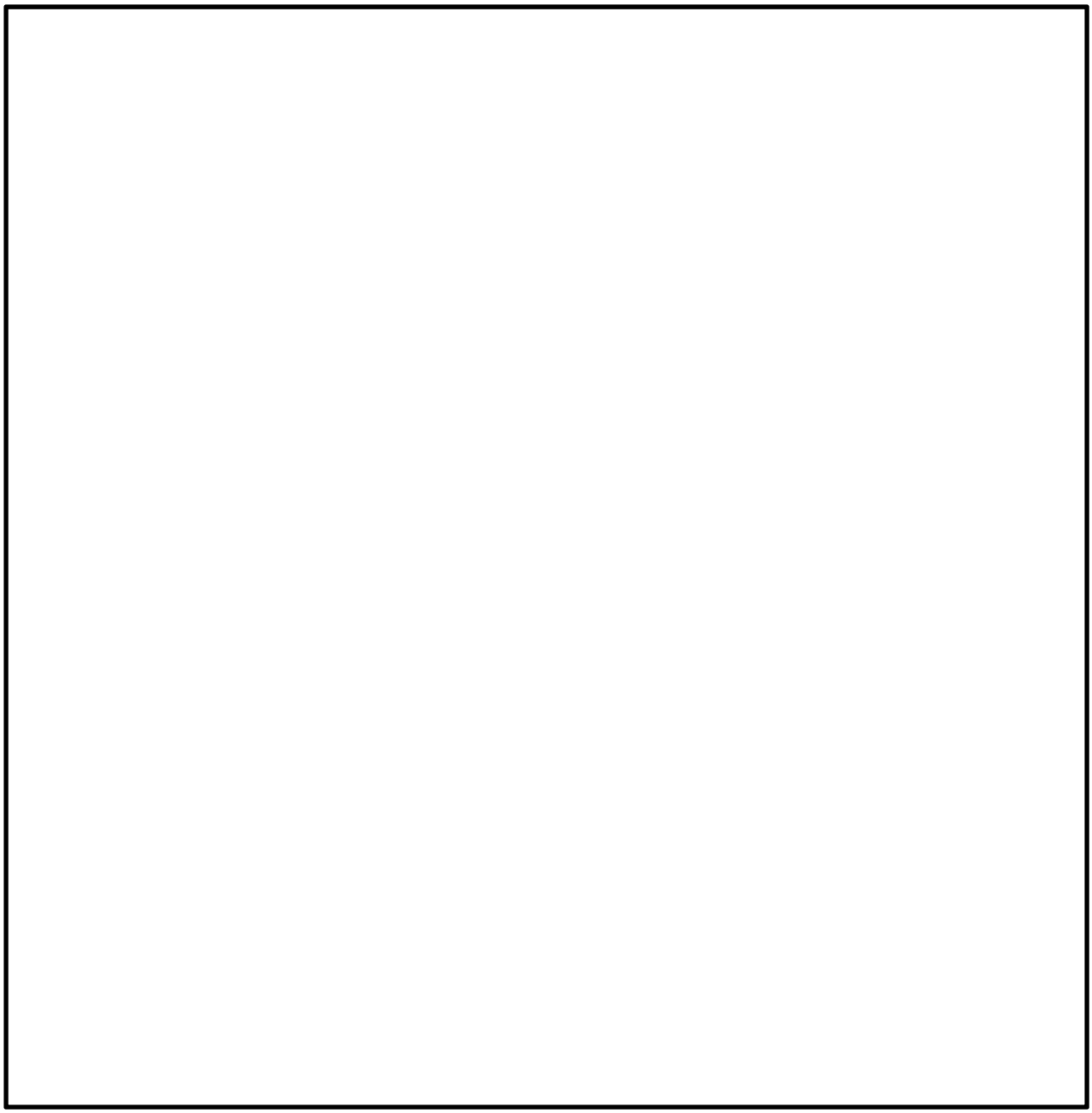
Market Drivers	Market Limiters

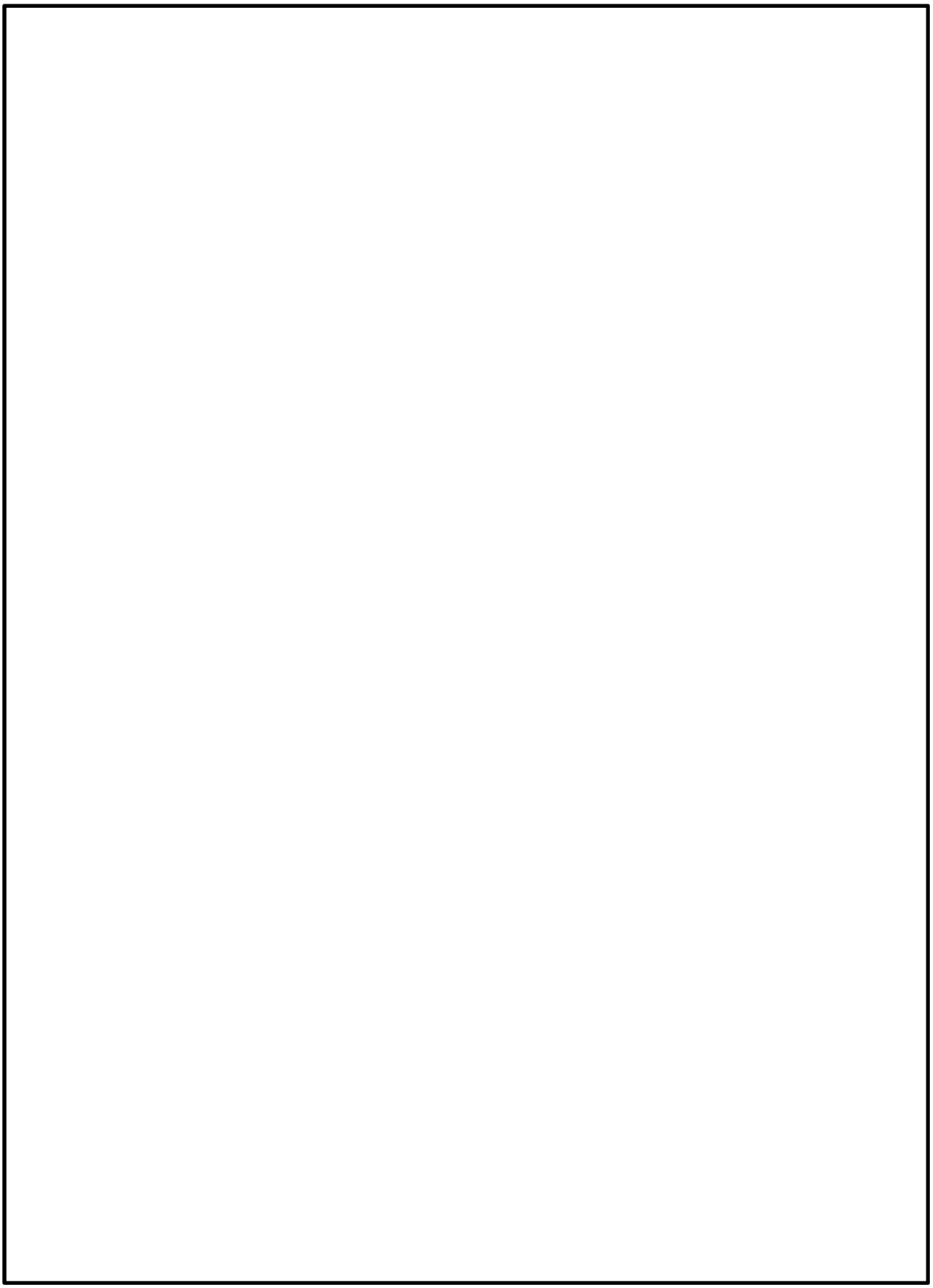
Source: iData Research Inc.

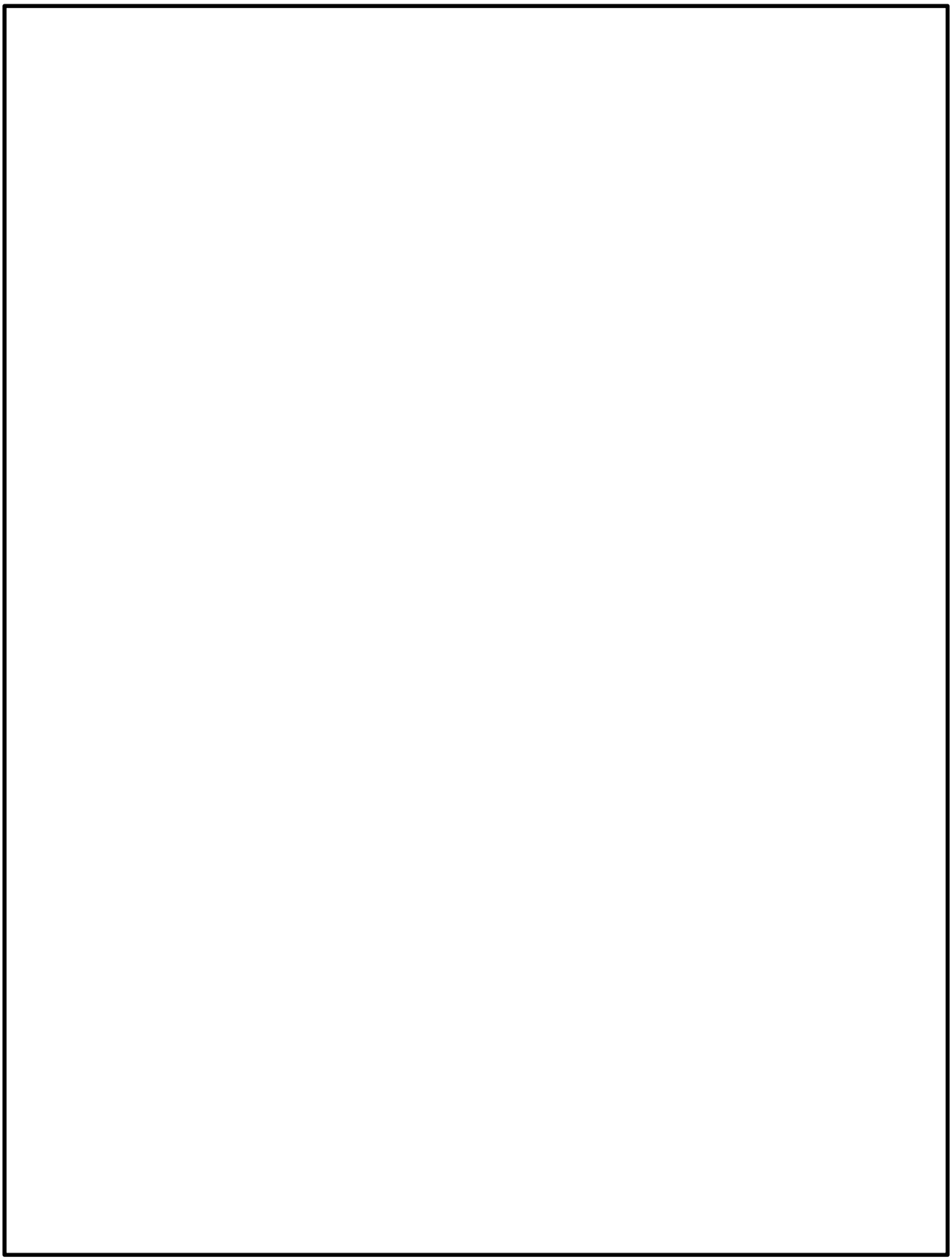
3.6 Competitive Analysis

Medtronic

In 2014, Medtronic led the U.S. MIS spinal implant market with a market share of X%. Medtronic was the leading competitor in the MIS interbody fusion and MIS pedicle screw markets with shares of X% and X% respectively. Medtronic held X% of the facet fixation market with their *ANCHOR FS™ Facet Fixation System.* The company also held a third leading market share of X% in the spinous process fixation market with its *CD HORIZON SPIRE™* device.







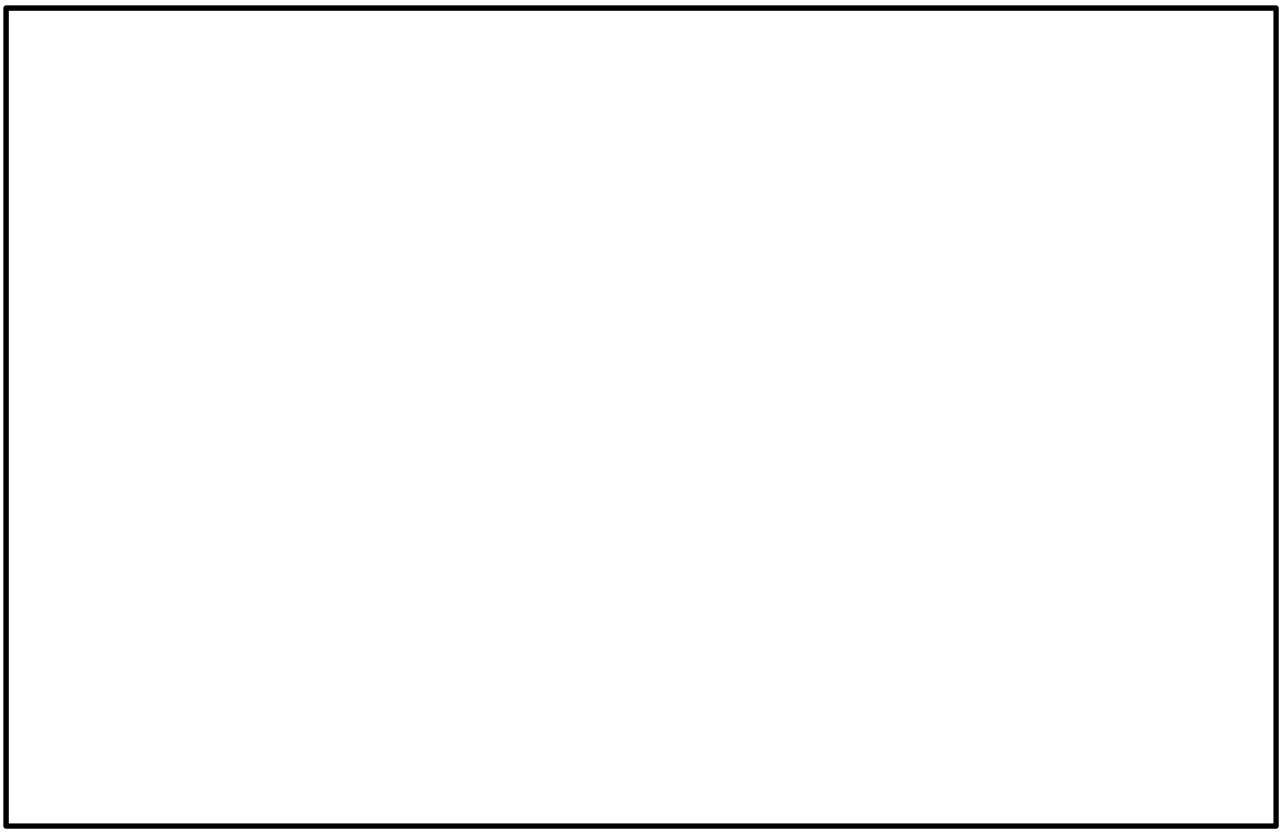


Figure 3-5: Leading Competitors, Minimally Invasive Spinal Implant Market, U.S., 2014

Company	Spinous Process Fixation Market	Facet Fixation Market	MIS Interbody Fusion Market	MIS Pedicle Screw Market	MIS Sacroiliac Joint Fusion Market	Total Market Share
Medtronic						

Source: iData Research Inc.

Chart 3-6: Leading Competitors, Minimally Invasive Spinal Implant Market, U.S., 2014

Source: iData Research Inc.

3.7 Mergers and Acquisitions

Zimmer to Acquire Biomet

Zimmer announced the $X acquisition of Biomet which is expected to close Q1 of 2015. Zimmer's absorption of Biomet will bring them access to multiple areas of the spine market. It will be interesting to see how the merger of two such large companies will play out in regards to the shift in market composition across the spine industry.