



GLOBAL SPINAL IMPLANTS MARKET

Report Extract

1 December 2015



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EXECUTIVE SUMMARY

Spine disorders are a leading driver of healthcare costs worldwide, and range in severity from mild pain and loss of feeling to extreme pain and paralysis. These disorders are primarily caused by degenerative conditions in the spine, deformity, tumors and trauma.

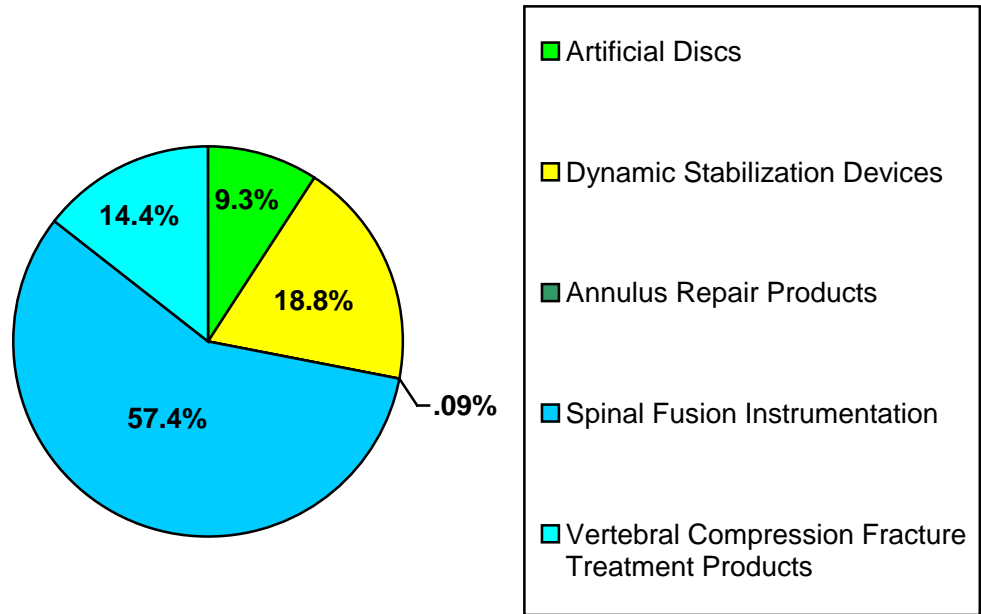
Degenerative disc disease (DDD) typically is caused by gradual disc damage and often results in disc herniation and chronic back or neck pain; the disease is most common among otherwise healthy people in their 30s or 40s and affects approximately half of the population in the 7 major markets aged 40 and older. Degenerative disc disease accounts for the large majority of operative conditions affecting the spine and typically results from repetitive stresses experienced during the normal aging process. The progression of DDD involves the gradual weakening and thinning of the shock-absorbing intervertebral discs. This condition can occur at any level of the spine, though it most commonly occurs in the cervical and lumbar regions. The progressive changes in the discs can lead to a host of conditions, including herniated discs, osteoarthritis, spinal stenosis, spondylolysis to name a few.

Although many patients who suffer from mild-to-moderate back pain opt for conservative, nonsurgical treatment, those with acute, debilitating pain often choose surgical intervention in an attempt to eliminate or reduce pain and restore quality of life. Depending on the patient's pathology, surgical decompression of the affected spinal segment often is sufficient to alleviate intractable pain caused by nerve root compression. However, decompression and fusion may be indicated to treat pain caused by spinal instability and severe disc degeneration.

Spinal decompression is performed to create adequate space for nerves in the spinal canal as a way to alleviate pain caused by neural impingement and may be performed in preparation for a fusion procedure.

Spinal fusion is performed to stop motion at one or more vertebral segments to eliminate pain and correct spinal instability. The goal of fusion is to decompress spinal nerves that are causing pain, restore the appropriate space between the vertebrae surrounding the diseased disc, and eliminate mobility of the affected

Exhibit ES-2: 2015, Global Spinal Implants Market, Share by Segment



Source: Medtech Insight

Exhibit 2-2: Selected FDA-Approved Cervical Total Disc Replacement Devices

Company	Device	Description	FDA Approval
Depuy Synthes	ProDisc-C	Features a ball-and-socket design; Composed of two cobalt-chromium alloy endplates and an ultra-high molecular weight polyethylene inlay; The endplates feature a zero-profile central keel and a plasma sprayed titanium coating	2007
Globus Medical	SECURE-C Artificial Cervical Disc	Features a two-piece design with a cobalt-chromium and polyethylene core; Inserted by initially securing the metal endplates to the adjacent vertebral body surfaces, followed by insertion of the core to allow translation	2012
LDR	Mobi-C Artificial Cervical Disc	Comprises of two metal (cobalt chrome) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fit between endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc at two adjacent levels that are causing arm pain and/or weakness or numbness	2013

(Continued)

Exhibit 2-2: (Continued)

Company	Device	Description	FDA Approval
Medtronic	Bryan Cervical Artificial Disc	Composite artificial disc designed with a polyurethane nucleus and two anatomically shaped titanium plates	2009
	Prestige ST Cervical Artificial Disc	Stainless steel device featuring two articulating components (a ball on top and a trough on bottom) that are inserted into the disc space and attached to the vertebral bodies on either side	2007
	Prestige LP Cervical Disc	The Prestige device is a stainless steel cervical disc composed of two articulating components (a ball on top and a trough on the bottom) that are inserted into the disc space and attached to the vertebral bodies on either side with bone screws; the device is implanted via an anterior surgical approach	2014
NuVasive	PCM DISC	Two-piece cervical disc with cobalt chromium outer plates and a polyethylene nucleus core; Available in three footprint and height options; The outer plates are designed with a serrated surface that is double-coated with a titanium/calcium phosphate to enable press-fit fixation and bony in-growth	2012

Source: Medtech Insight

Exhibit 2-3: Selected FDA-Approved Lumbar Total Disc Replacement Devices

Company	Device	Description	FDA Approval
B.Braun Melsungen	ActivL	Titanium-polymer-titanium composite device with semi-mobile central disc; Translational movement is designed to minimize biomechanical stress at the facet joints; Available in keel and non-keel configurations; Features an implant height of 8.5mm and a 2.0mm anterior/posterior translation; Constructed of a plasmapore coating and a calcium phosphate layer for additional stability	2015
DePuy Synthes	InMotion	Modified version of the Charité device; Features single-piece insertion technology and lateral fixation teeth	2010
	ProDisc-L	A modular implant consisting of two endplates and a polyethylene inlay with the endplates (one inferior and one superior) manufactured from cobalt chromium alloy; The implant is secured to the vertebrae via central keels that are part of the top and bottom endplates; The superior endplate is available in 2 sizes (medium and large) and 2 lordotic angles (6° and 11°)	2006

(Continued)

Exhibit 2-3: (Continued)

Company	Device	Description	FDA Approval
LDR	MobiDisc	Second-generation unconstrained metal-on-polyethylene artificial lumbar disc; Features a self-centering load-sharing design that reduces stress on the posterior articular process; For both anterior and anterolateral access	Available in Europe
Spinal Kinetics	M6-L	Consists of 2 titanium outer plates, an artificial nucleus, an annulus, and a sheath; The artificial nucleus is constructed of polycarbonate urethane and is surrounded by a woven polyethylene fiber annulus; Allows a controlled range of motion in 6° of freedom	Launched in Europe in 2010

Source: Medtech Insight

5. SPINAL FUSION INSTRUMENTATION

Spinal fusion is a surgical procedure that is performed to stabilize an unstable portion of one or more vertebral segments to stop abnormal motion of the vertebrae thought to be the source of pain. It is also used to correct deformities. Spinal fusion surgery uses bone grafting to enable two opposing vertebrae to fuse, as well as instrumentation to help join the vertebrae together and restore stability. The goal of the surgery is to allow two adjacent vertebrae to grow and fuse together.

Typically approximately 85-90% of spinal surgeries involve fusion and this phenomenon is seen across markets. According to a report by the Agency for Healthcare Research and Quality (AHRQ), approximately 488,000 spinal fusions were performed during U.S. hospital stays in 2011, which accounted for 3.1% of all operating room procedures. (Weiss, AJ, et al.) More recent data from the same agency reported that in 2013 the number of discharges made on spinal fusion procedures was 406,735, with an average stay of 3.7 days.

Spinal fusion procedures are categorized into instrumented and non-instrumented. Non-instrumented procedures are those in which there are no implants used and the bones are left to fuse without the devices. Spinal fusion using instrumentation and internal implants is the gold standard of treatment.

A typical fusion procedure involves the implantation of a plate or screw/rod fixation system, and/or an interbody device to replace the intervertebral disc between the indicated vertebral bodies to be fused, which help increase stability and promote fusion in the indicated vertebral segment.

Spinal fusion instrumentation is used in various combinations in spinal fusion procedures to treat a diverse range of degenerative spinal disorders and deformities. Next to trauma-related low back pain, the most common spinal disorder is degenerative disc disease (DDD). Spinal fusion also may be used to relieve back pain caused by other conditions including fracture, infection, scoliosis, spinal stenosis, spondylolisthesis, or tumor(s).

In order to obtain a fusion, certain basic criteria must be met in the bony surface:

- a suitable graft must be available to serve as the bridge to connect the vertebra;

Company Listing**Alphatec Spine**www.alphatecspine.com**Amedica**www.amedica.com**Atlas Spine**www.atlasspine.com**Axiomed Spine**www.axiomed.com**B. Braun Melsungen AG**www.bbraun.com**Benvenue Medical**www.benvenuemedical.com**Biotechni**www.biotechni.com**Carefusion**www.carefusion.com**Crosstrees Medical**www.xtreesmed.com**DiscGenics**www.discgenics.com**Depuy Synthes/Johnson & Johnson**www.depuysynthes.com**DFINE**www.defineinc.com**Exactech**www.exac.com**Globus Medical**www.globusmedical.com**Heraeus Medical**<http://heraeus-medical.com>**Integra LifeSciences Corp.**www.integralife.com**Intrinsic Therapeutics**<http://in-thera.com>**ISTO Technologies**www.istotech.com**K2M**www.k2m.com**Life Spine**www.lifespine.com**LDR**www.ldr.com**Medicrea**www.medicrea.com**Medtronic plc**www.medtronic.com**Mekanika**www.mekanika.com**Mesoblast, Ltd.**www.mesoblast.com**NuVasive, Inc.**www.nuvasive.com**Ortho Development**www.odev.com**Orthofix**www.orthofix.com**Orthopaedic & Spine Development**www.osdevelopment.fr**Osseon, LLC**www.osseon.com

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