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SOFAMOR DANEK GROUP, INC.

(SDG)

May 21, 1998 (98-033)
Basic Report

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Price: $87 13/16 ($39 1/8–$89 5/8)
Fiscal Year Ends: December

Fiscal Year	Earnings Per Share*	Price/Earnings Ratio
1996	$1.68	52.4x
1997	$2.12	41.5x
1998E	$2.57	34.2x
1999E	$3.14	28.0x

Earnings Per Share Growth*		Return on Average Equity	
1993-1997	15%	1993-1997	19%
1997-1999E	22%	1998E	25%

Net Debt/Total Cap. (3/31/98):	6%	Dividend:	None
Book Value Per Share (3/31/98):	$11.64	Common Shares:	27.9 million
Insider Ownership:	24%	Market Value:	$2.4 billion
Sales (1998E):	$374 million		

* Excludes special charges

Investment Opinion: Long-term Buy

Sofamor Danek Group is the world's leader in the $900 million spinal device market, part of the $8 billion total market for orthopedic devices. SDG has the broadest range of devices for spinal and cranial surgery and a 42% market share of the $630 million spinal implant market—the largest spine segment. The spinal device market is growing rapidly, driven by the drive to reduce the effects of the aging population on increased spinal problems, improved technology, increased use of instrumentation, the total cost of back problems, and international penetration and growth. In the core spinal implant market, SDG is the best-positioned competitor with its top three products lines, the TSRH® and CD™ spinal instrumentation systems, as well as the Orion™ anterior cervical plate system, each having sales larger than most competitors' total sales. Moreover, SDG has the strongest pipeline in the fastest-growing subsegment, interbody fusion cages. New, complementary market segments in areas such as image-guided surgery and bone growth enhancers provide SDG with additional significant growth opportunities. In addition, SDG benefits not only from growth trends in the United States, but also internationally, where it has a strong presence. All these trends should lead to superior financial results for Sofamor Danek. We recommend purchase of this high-quality medical device company.

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Summary of Investment Recommendation

Sofamor Danek Group, Inc. is the world's leading spinal device company, providing implants, computer-assisted and minimally invasive surgery systems, and bone growth enhancers. It maintains a 35% share of the $900 million overall market and a 42% share of spinal implants, the largest segment of spinal devices. This segment alone constitutes approximately $630 million, with the United States accounting for two-thirds of the total. We expect that this core target segment—implants—should continue to expand rapidly, reaching almost $1 billion in size by 2000. Also, SDG has built on its strength in the implant segment to assemble an extensive, comprehensive product line covering the entire spine and cranium, with more products than any other competitor. Lastly, SDG has a strong position in international markets, which adds to its growth prospects. As a result of SDG's strengths and strategies, its financial and stock performance has been superior.

Our investment recommendation for SDG is on the basis of the following five key factors.

- SDG is the world's leader in the growing market for spinal and cranial devices.
- SDG remains the best-positioned competitor in the core and largest spinal device market segment—implants and instrumentation.
- The core implants and instrumentation market segment continues to expand rapidly.
- SDG is creating more growth opportunities by continuing to add new types of products for the same target-customer segments.
- SDG has a strong international position that provides it with additional growth opportunities.

Worldwide Leader in Spinal Devices

SDG has the most comprehensive product line of any competitor, leading to a 35% market share of the total $900 million spinal device market. Its leading position is supported by a loyal customer base of surgeons, for whom SDG will manufacture a custom implant or instrument "special," typically with a two-week turnaround. SDG seeks to "surround" the spinal and cranial surgeons with all the high-value products that they need for a particular case. To that end, the company has the broadest complementary product line of any competitor. To maintain its lead in both breadth and innovation, SDG has active research and development, which has resulted in 348 patents and 422 patents pending at the end of 1997. In addition, SDG has made a series of targeted acquisitions and licensing agreements, as well as divested noncore businesses to strengthen its core position. Lastly, to facilitate even better use of its products, SDG provides the most comprehensive package of physician- and patient-support services, such as practice-management tools, coding assistance for billing and reimbursement, cost-justification analysis for capital equipment, automated outcomes tools, and patient education materials.

Best-positioned Competitor in the Core Spinal Implant and Instrumentation Segment

SDG is currently the overwhelming market share leader with 42%, almost 2 times the size of its next-largest competitor, the recently merged DePuy Motech/AcroMed combination. It has two well-established, extremely successful middle- and lower-back instrument lines, TSRH® and CD™, with steady sales of about $80 million and $50 million, respectively. Each product line is the size of almost any other spine competitor's total sales. In addition, SDG continues to innovate in these established product lines. The company also has developed other middle- and lower-back systems. In the cervical spine area, SDG has had a phenomenal success with the Orion® anterior cervical plate system, increasing sales from about $5 million in 1994 to more than $34 million in 1997, a compounded annual

growth rate of greater than 90%. Lastly, while SDG has not yet received FDA clearance for one of the most popular spinal implant products—interbody cages—for spinal fusion, its pipeline still makes it best-positioned, in our opinion, for eventual leadership in this key, rapidly growing segment.

Largest Spinal Device Market—Implants and Instrumentation—Continues to Grow Rapidly

The core spinal device segment—implants and instrumentation—is currently $630 million globally and should expand to almost $1 billion by 2000. This growth is propelled by five factors. First, the total cost and overall burden of back conditions and injuries are enormous, with direct and indirect costs currently approaching $100 billion worldwide. Second, the aging of the population is creating a larger pool of individuals who are likely to suffer these difficulties. For example, most back injuries affect those age 45-64 years old, and this population will increase by 20 million individuals in the United States alone during the next 10 years. Third, instruments allow for and enhance the results of surgical interventions to address the conditions (for example, most estimates show a 50%-100% increase in fusion success), in addition to improvements in function and reductions in pain. Fourth, the rate of spinal fusions per capita continues to increase. Lastly, there are still many fusion procedures that do not yet use instruments.

Creating More Growth Opportunities

The company continues to add new types of products for the same target-customer segments, which helps to ensure its leading position. Building on the core spinal implant segment, SDG has established positions in four other related businesses: image-guided surgery, bone growth enhancers, discectomy, and cranial. These products are sold to the same target customers—orthopedic surgeons and neurosurgeons—who are spine specialists. The result of successfully adding these complementary product lines has been accelerated growth beyond that produced by implants alone.

Strong International Position Provides Additional Growth

Its international sales in 1997 were greater than $100 million, making its sales outside of the United States larger than the total worldwide sales of the previously next-largest competitor, AcroMed. Prior to its 1993 merger with Sofamor, approximately 10% of Danek's sales were international; now about one-third are. This was accomplished through building on Sofamor's historical presence in Europe and elsewhere throughout the world to assemble a very strong international sales and distribution organization. It comprises 200 independent representatives in countries where SDG has its own affiliates. In addition, in approximately 56 other countries, SDG has stocking distributors. All of this has led to international sales growth of more than 20% per year from 1994 to 1997 and should lead to overseas growth of 23%-25% for the near future.

Risks

Regulatory. Medical devices, such as spinal implants and surgical systems, are subject to government regulations in most countries. Therefore, SDG's success in part hinges on its ability to achieve the necessary approvals, as well as the time and expense of attaining those approvals. With some limited exceptions, such as custom implants, all SDG's implants marketed in the United States are covered by 510(k) procedures (see appendix E). This FDA premarket notification process requires that new devices are shown to be substantially equivalent to devices marketed prior to 1976. As devices become increasingly more innovative, this threshold may be more difficult to attain, consequently potentially requiring the more in-depth premarket approval (PMA) which would include human clinical trials, thereby increasing time, cost and risk or approval.

The FDA also has taken a strict approach to marketing and package labeling of devices that are attached to the spinal pedicles using screws (see below). Warnings must be included for these devices regarding potential risks and any unestablished benefits.

Product liability. In general, medical device manufacturers always face a risk of product liability litigation and whether they will have or be able to retain sufficient insurance to cover any claims. In the specific case of spinal implant manufacturers, there has been ongoing litigation regarding the use of pedicle-screw fixation devices.

Pedicle screw litigation (see appendix F). In 1994, SDG, along with other spinal implant companies, was named in a purported class-action product-liability lawsuit alleging that patients were injured by spinal implants—pedicle screws that the company manufactured. In February 1995, Judge Louis Bechtle denied class certification for the suits. He subsequently dismissed certain claims of conspiracy and fraud without prejudice on procedural grounds. In December 1996, AcroMed, SDG's largest competitor, established a $100 million settlement fund to settle the claims against it. In January 1997, SDG took a pretax charge of $50 million to cover the uninsured costs relating to the product liability lawsuits, including the costs to continue to defend against the suits. Until now, the costs of defending the claims have been paid principally by the companies that insure SDG. However, insurance policies must be renewed, and there is no guarantee that such policies always will be available to the company. As of December 1997, there were approximately 2,800 plaintiffs involved in product liability lawsuits, with an additional 2,600 claimants in lawsuits alleging that SDG, along with competitors, conspired to promote the use of spinal implant systems illegally. As of now, the court has allowed for the federal trial courts to consider each state's laws to determine if there were conspiracies among manufacturers, medical societies, and certain physicians to conceal relevant information from surgeons.

Financials

SDG's financial results should remain outstanding, providing more than 20 percent net income growth. The company's sales have grown rapidly over the last five years, from $76 million to $313 million, a compounded annual growth rate of 21%. During that time, SDG experienced excellent operating and net income margins, averaging 27% and 18%, respectively. We believe this performance should persevere, with continuing significant cash generation and rising income. Thus far, this performance has resulted in five-year compounded annual growth in net income of 20%, adjusted for one-time charges, and in our opinion, should continue, resulting in net income growth of significantly more than 20% per year for 1998 and 1999. SDG's balance sheet, which historically has been strong, should continue to improve, due both to its recent equity offering and its strong earnings. Currently, the company's ratio of long-term debt to total capitalization is only 6%. Its financial position gives it the capacity and flexibility to acquire other products, intellectual property, or businesses that would further enhance its growth by leveraging its superior position in the spinal and cranial device segment.

The Company

Sofamor Danek was founded in 1983, as Biotechnology, Inc., by Dr. George Rapp, an Indianapolis orthopedic surgeon, and L.D. Beard, the former chairman of Richards Medical Company, to make orthopedic implants. The company contracted with, and soon purchased in 1983, Warsaw Orthopedic, a machine shop run by Miles Igo in Warsaw, Indiana, that manufactured products for major orthopedic firms on an original-equipment-manufacturer basis. For sales and marketing, Allen Olsen, also formerly with Richards Medical, joined via the acquisition of his firm, Danek, in 1985. Mr. Olsen brought on board 20-30 independent representatives and began developing the strong relationships with surgeons that Sofamor Danek still enjoys today. In 1987, the company began focusing on spinal implants. Spinal implants and instruments are used predominantly to fuse two or more vertebrae to restabilize the spine or fixate bone so that it may regrow or reunite following, for example, fracture or tumor removal. In 1990, the company changed its name from Biotechnology, Inc. to Danek Group, Inc.

Has Created a Spinal Device Powerhouse Merging Danek with Sofamor

In 1993, Danek merged with Sofamor (Societe de Fabrication de Materiel Orthopedique) to form the Sofamor Danek Group. Sofamor had been founded in the late 1970s as an orthopedics company. In the early 1980s, it began focusing on the spine to replace the Harrington rods that were held in place by wire. Surgeons would use these or often no implants at all in an attempt to achieve fusion, resulting in limited success. Sofamor had developed the Cotrel DuBousset system, including rods, hooks, and transverse traction devices. This merger provided many benefits, including an increased international presence, a greater patent estate, and more critical mass and infrastructure to enhance growth. In addition, it was also a strategic, defensive move to prevent another competitor from leap-frogging Danek by acquiring Sofamor.

More recently, SDG has been active in other acquisitions and licensing activities that have broadened its presence in the spine beyond fixation products significantly. It has grown from supplying spinal implants and instrumentation, to providing discectomy, cranial, image-guided surgery, and biological enhancing products, truly becoming "The Spinal Specialist." Figure 1, on the facing page, enumerates the company's products and where in the axial skeleton they are used. The comparison in figure 2 of SDG's product lines to that of its competitors shows that SDG maintains the most comprehensive set of products targeted at this market segment.

Much of this focused product line expansion has been done through a series of targeted acquisitions, divestitures, and licenses as shown in table 1, on page 8. In 1989, Danek licensed the TSRH® spinal implant system, its most successful product, and in 1992, it acquired the minimally invasive MED microendoscopic discectomy system. Then in 1993, as mentioned above, Danek merged with the other leading spinal device implant company in the world, Sofamor. To continue to expand beyond only spinal implants, in 1995, SDG licensed the rhBMP-2 bone-growth factor from Genetics Institute to enter the bone-growth enhancing market and, in 1996, entered into a collaboration with the University of Florida Tissue Bank, which has led to an injectable bone paste, Ostefil™ and other allograft bone parts, such as the MD cortical bone dowels. To enter the image-guided surgery market, SDG acquired Surgical Navigation Technologies in 1996, and built on that platform through agreements with Vista Medical Technologies in 1997 for a head-mounted, 3D display, and with GE Medical in 1998 to market a real-time MRI system. SDG also entered the cranial market in 1996 with the acquisition of two more product lines, TiMesh titanium plates and screws and MedNext powered surgical drills.

Figure 1
Sofamor Danek Group, inc.
Comprehensive Spinal Product Line

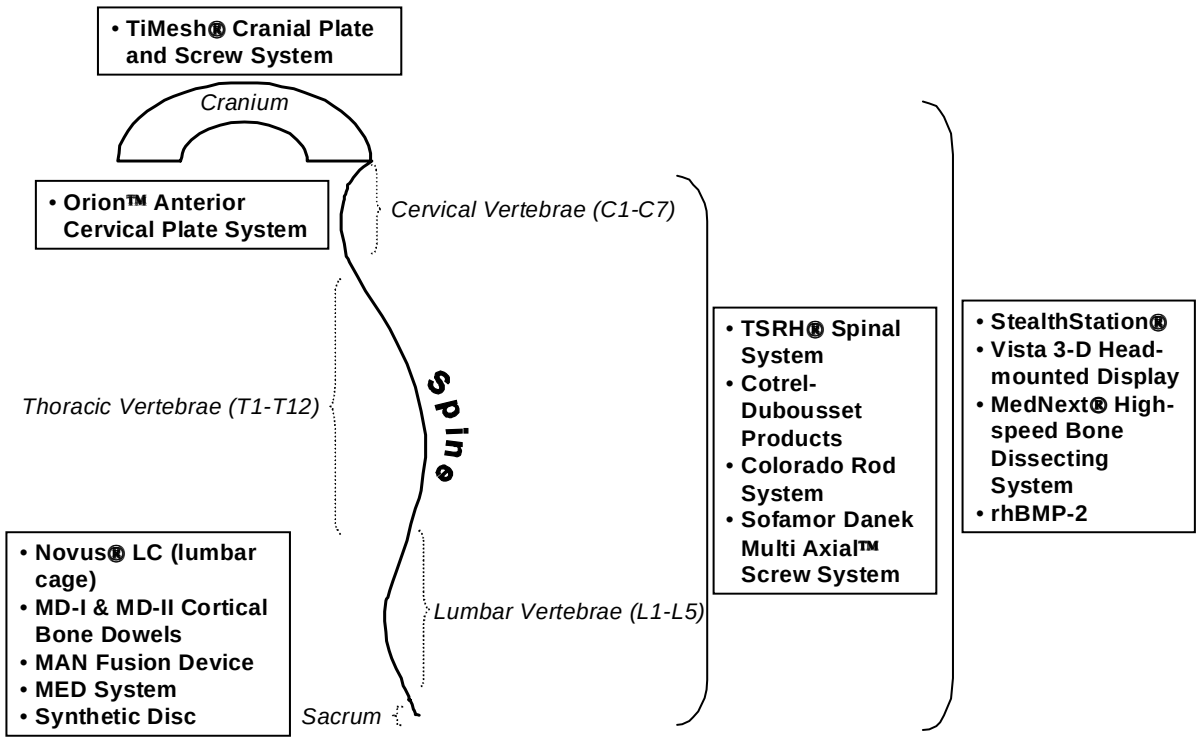


Figure 2
Sofamor Danek Group, Inc.
Competitor Product Lines

Company	Lumbar/ Thoracic Instruments	Cervical Systems	Interbody Fusion Cages*	Cranial	Bone Graft Substitutes**	Bone Growth Factors	Image Guidance Systems	Discectomy Systems	Synthetic Discs
Sofamor Danek (SDG)	☒	☒	×*	☒	×**	×	☒	☒	×
DePuy Motech / AcroMed (DPU)	☒	☒	×*		×**		☒	☒	×
Aesculap	☒	☒	×	×				×	×
Interpore Cross Medical (BONZ)	☒	×	×		☒	×			
Osteonics / Dimso / Stryker Biotech (SYK)	☒	☒	×	☒		×			
Synthes	☒	☒	×	☒					×
Surgical Dynamics (USS) / Smith & Nephew (spine)	☒	×	☒					☒	
Howmedica / Leibinger (PFE)	×			☒	×				×
Wright Medical	☒	☒			☒				
Codman (JNJ)		☒						☒	
Osteotech (OSTE)	☒		×*		×**				
SM Spine-Tech / SM Biologics (SM)			☒			×			
Elekta							☒		
Midas Rex				☒					
Radionics							☒		
Raymedica									×
Zeiss							☒		
Zimmer (BMY)	☒				☒				

☒ FDA approved; × Not FDA approved or developmental

*Includes threaded cortical bone dowels (these do not require FDA approval; DePuy also has off-label sales of its mesh cage
**Allografts do not require FDA approval as they are human tissues

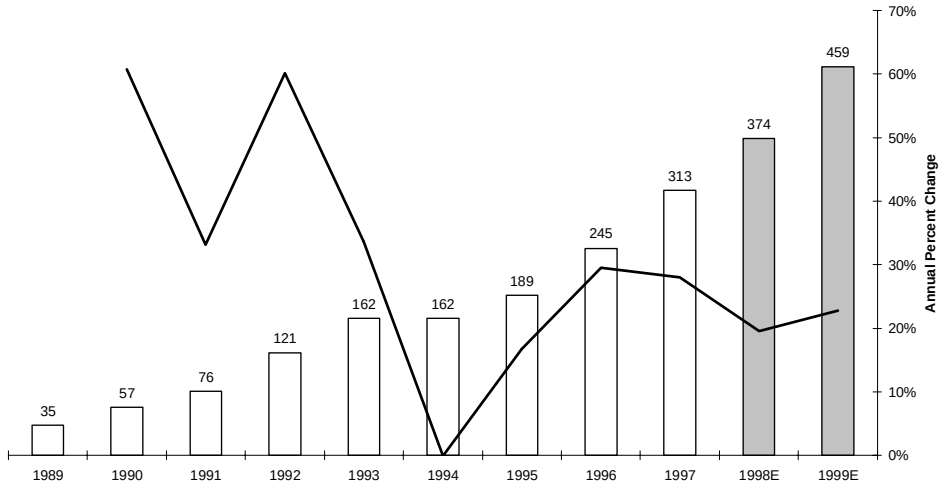
Source: Various company financials; FDA; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Table 1
Sofamor Danek Group, Inc.
Business Development Activities

Year	Company	Venture
1989	Texas Scottish Rite Hospital	License TSRH System of spinal implants
1991		Sold majority of orthopedic softgoods business (splints, slings and pressure bandages) and phased out the rest.
1992	Citation	Acquired MED System
1993	Sofamor	Merged two leading spine companies
1995	Genetics Institute	Acquired North American rights to rhBMP-2 (a bone growth factor) for spinal applications
1995	Implex	Exclusive worldwide rights to use Hedrocel™ (open pore tantalum structure material) for spinal applications
1996	Surgical Navigation Technologies (SNT)	Acquired SNT, a developer of frameless computer-aided surgery systems (StealthStation) for image-guided surgery
1996	TiMesh	Acquired certain assets used to design and manufacture titanium plates and screws
1996	MedNext	Acquired this developer of powered surgical instruments (e.g., drills)
1996	University of Florida Tissue Bank (to be renamed Regenerative Technologies)	Exclusive worldwide agreement to provide services related to (threaded) cortical bone dowels. Since, extended to include Osteofil™ injectable bone paste and Cornerstone™ bone block spacers
1996	Colorado	Acquired this developer of spinal implants
1997	Vista Medical Technologies	Exclusive worldwide alliance to distribute the StereoSite head-mounted, 3-D image display for head, neck, and spinal applications for use with StealthStation
1998	MAN Ceramics	Acquired assets related to carbon fiber fusion device
1998	GE Medical Systems	Exclusive U.S. rights to market GE's real-time surgical MRI system, the Signa SP IntraOperative Magnetic Resonance System™

The results of SDG's efforts have been impressive. Its revenue has increased from $35 million in 1989 to $313 million in 1997, with forecast revenue of $459 million by 1999 (see figure 3). This is a compounded annual growth rate, sustained for a decade, of about 30%.

Figure 3
Sofamor Danek Group, Inc.
Revenue and Growth Rate
($ in millions)



Source: SDG financials; William Blair & Company, L.L.C. analysis

Has Assembled Strong Domestic and International Marketing, Sales, and Distribution

We believe that SDG has a superior, comprehensive approach to selling to spine surgeons, calling on both subspecialties that treat the spine, supplying a full-range product offering that better meets their need and providing extensive support programs to facilitate product selection and use. To begin with, surgical interventions in the spine and cranium are performed by both orthopedic surgery and neurosurgeon subspecialists. Orthopedic surgeons treat knees, spines, hips, shoulders, hands, and feet. Neurosurgeons treat injuries, traumas, and tumors of the head, brain, spinal cord, and nerves. Orthopedic surgeons represent about 70% of the market, and neurosurgeons 30%. Therefore, SDG traditionally has focused more on spine surgeons who came from orthopedic surgery; however, for several years it also has been courting neurosurgeons aggressively. For example, two of the new product additions are targeted directly at neurosurgery, the TiMesh® cranial plate and screw system, and the cranial software package for the StealthStation®. In addition, three other product lines are useful for neurosurgeons (and orthopedic spine surgeons also): the MedNext high-speed bone dissecting system, the Orion® cervical plate system, and the MED system. The MedNext system has an antikick feature that neurosurgeons particularly appreciate when drilling into the cranium. In addition, neurosurgeons perform many of the laminectomies/discectomies, so they like the MED system, the only microendoscopic system for midline approach. In contrast, other competitors sometimes focus on and have strengths regarding the two specialties. For example, Spine-Tech focuses on orthopedic surgeons for its BAK fusion cage, and Surgical Dynamics is focused on neurosurgeons for the RayCage (Dr. Ray is a neurosurgeon). In image-guided surgery, Radionics is focused on neurosurgery, since it started with a framed stereotactic system for the cranium and also produces a lesion generator to treat such diseases as Parkinson's.

To address the surgeons' various needs for more-frequent use of SDG's products, as well as the specific needs of patients and institutions, such as hospitals and clinics, SDG has established various high-value marketing and support programs. These programs complement the comprehensive product line to "surround" the surgeon. As mentioned earlier, SDG typically will manufacture a custom implant for a surgeon in two weeks. In addition, one of its major strategic thrusts is to provide the most-comprehensive package of physician- and patient-support services—i.e., a complete range of practice-management tools, coding assistance for billing and reimbursement, cost-justification analysis for capital equipment, automated outcomes tools, and patient education materials. Also, the company has created various purchasing options for institutions, including its "loaner program." For example, an entire implant system is shipped overnight for next-day surgery, and the customer is charged only for the parts used, in addition to an appropriate premium to cover administrative costs.

SDG has approximately 400 sales representatives worldwide, plus distributors, calling on spine surgeons. In the United States, SDG has 175 independent and 25 direct sales reps. The remaining 200 independent reps are located in countries where SDG has its own affiliates (see table 2, on the next page); the company has stocking distributors in approximately 56 other countries. In addition to these representatives that sell spinal implants and instruments, the company has sales representatives in its image-guided surgery division (Surgical Navigation Technology) that are focused on capital equipment sales.

Table 2
Sofamor Danek Group, Inc.
Recent Senior Management Additions

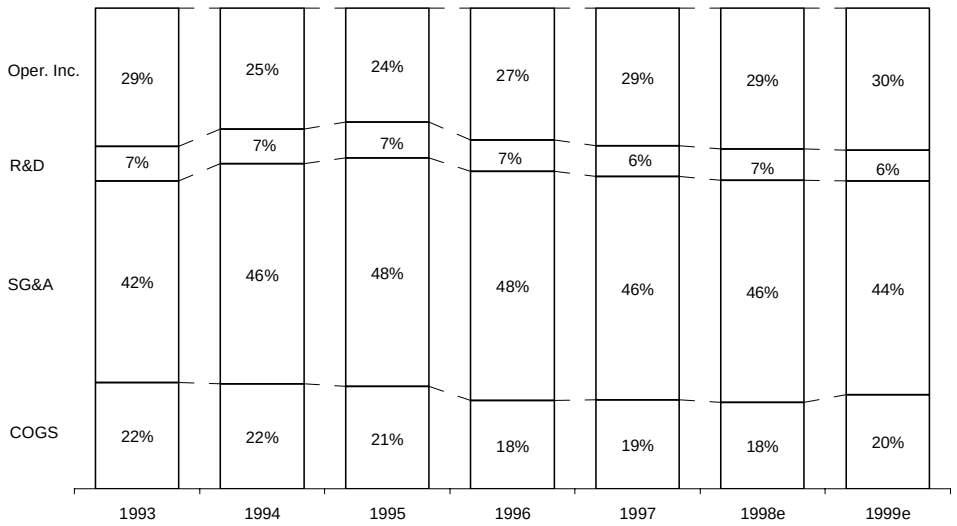
Senior Manager	SDG Position	Year Hired	Former Position	Former Organization	Other Firms
Richard Mazza	Exec. VP Operations	1998	COO	Wright Medical Technology	U.S. Surgical
Robert A. Compton	President and COO	1997	Venture Capitalist	CID Equity Partners	
George G. Griffin, III	Chief Financial Officer	1997	CFO and Executive VP	Wright Medical Technology	Smith & Nephew
Kenneth G. Hayes	President – Image Guided Surgery	1997	President	USCI Division of C. R. Bard	Ethicon (J&J)
Mark D. LoGuidice	Exec. VP – New Products & Markets	1995	VP Marketing – Sutures	U.S. Surgical	
Edward Traurig	Exec. VP – Sales	1995	Various	U.S. Surgical	
Don W. Urbanowicz	Exec. VP – Marketing-USA	1995	President – Perry Surgical Glove Division	Smith & Nephew	Howmedica (Pfizer)
E. R. (Ron) Pickard	Chairman and CEO	1994	President – Orthopedics Division	Richards Medical (now Smith & Nephew)	
R. L. (Lew) Bennett	Senior VP	1991	VP – Marketing (U.S., Canada and Far East)	Richards Medical (now Smith & Nephew)	Howmedica (Pfizer) Ethicon (J&J)
Laurence Y. Fairey	President – International Division	1991	VP – International Operations	Richards Medical (now Smith & Nephew)	
John Pafford	Exec. VP – Global R&D	1991	Various	Dow Corning Wright	

Prior to 1993 and the merger with Sofamor, approximately 90% of Danek's sales were in the United States. The merger brought a good international network of stocking distributors. Afterward, SDG cherry-picked between the Sofamor and Danek distributors and began conversion to local affiliates using independent reps where feasible. The switch to more direct selling has contributed to improved gross margins from 78% in 1994 to 81% in 1997. Although this initially was offset partially by a subsequent increase in selling, general, and administrative expenses, from 46% of revenue in 1994 to 48% through 1996, SG&A fell back to 46% in 1997, and we estimate that it will decline further to 44% by 1999. In the future, these salesforce- and distribution-driven margin improvements will be useful in offsetting the effects of an expected mix shift to lower-margin capital equipment, which we believe will reduce gross margins back to 80% (see figure 4, on the facing page).

Has Continued to Build Strong Senior Management

We believe that SDG has proven that it has a very strong management team. However, the critical issue is how it will maintain strong management in the face of such exceptional growth. To achieve the depth required for this growth, SDG successfully and continuously has recruited excellent external candidates with records in other successful, high-quality, related organizations (see table 3, on the facing page). With the depth thus far and proven ability to attract great talent, SDG is well-positioned to continue to manage its impressive growth, in our view.

Figure 4
Sofamor Danek Group, Inc.
COGS and Operating Expenses*



*Adjusted for one-time charges

Source: SDG financials; William Blair & Company, L.L.C. analysis

Table 3
Sofamor Danek Group, Inc.
Worldwide Affiliates

European Division (includes Africa and the Middle East)	Americas, Asia Pacific (AAP)
• Benelux	• Australia
• France	• Canada
• Germany	• Hong Kong
• Italy	• Japan (50% owned)
• South Africa	• Korea (50% owned)
• Spain	• Puerto Rico
• United Kingdom	

The Market for Medical Devices of the Spine

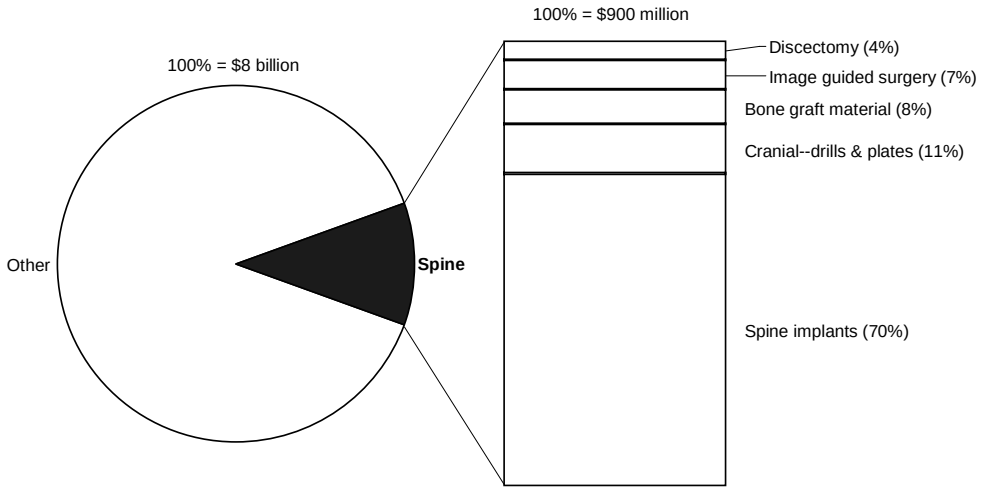
In addition to the market size and growth prospects for medical devices of the spine, it is useful to understand certain clinical and product concepts for this market, such as the spine's anatomy, the target surgeons, the conditions that are treated, and the devices that are used. We address market sizes and growth prospects below. In appendices A through C, we discuss relevant anatomy and medical conditions and provide more detailed information on the devices.

Market Size and Growth Prospects

Overall market sizes. As shown in figure 5, on the next page, the global market size for medical devices of the spine and cranium is approximately $900 million, or about 11% of the $8 billion orthopedics market. The major markets are implants, instrumentation, and cranial products, including drills and titanium mesh, bone graft materials, equipment for image-guided surgery, and discectomies. While the market for spinal devices in the United

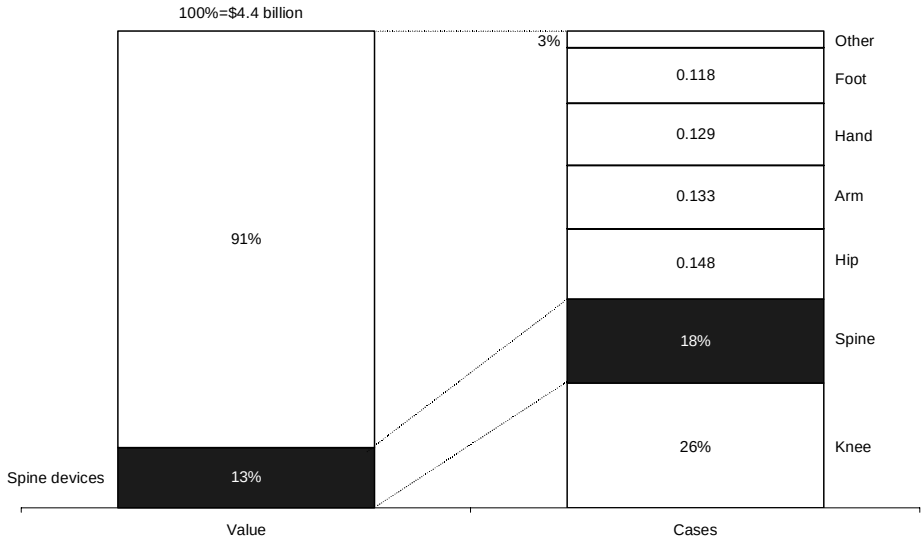
States represents only about 13% of the value of the $4.4 billion U.S. orthopedics market, spinal conditions represent 18% of the cases (see figure 6). Also, as illustrated in figure 7, 64% of the total market value is in the United States; however, the geographic concentration varies considerably by subsegment. For example, the 2:1 ratio for the United States to the rest of the world (ROW) is also true for spinal implants and image-guided surgery, however, for the cranial and discectomy markets, the geographic distribution is 50:50, and for commercial bone graft materials, 80% of the value is in the United States.

Figure 5
Sofamor Danek Group, Inc.
Market Size for Spinal Segment of Orthopedics



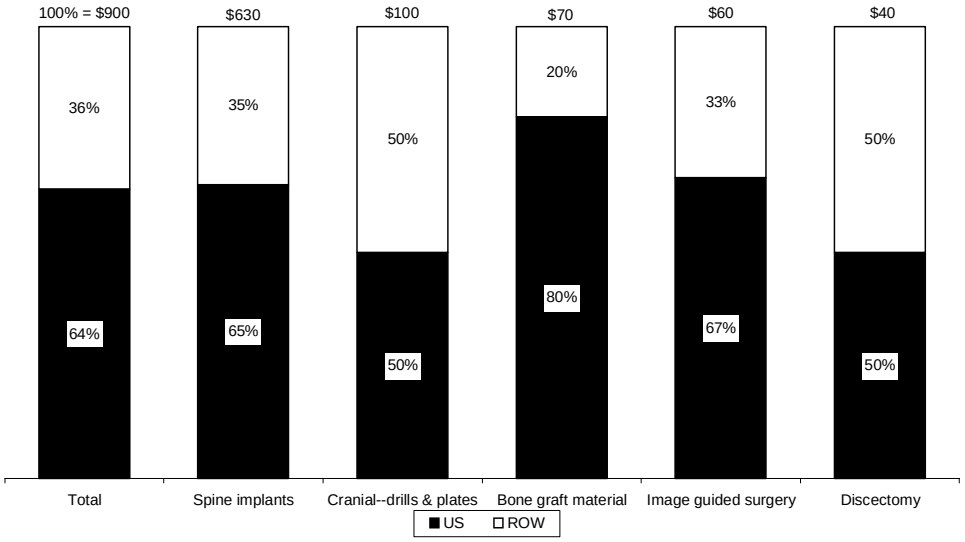
Source: Various company financials; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Figure 6
Sofamor Danek Group, Inc.
Value of U.S. Spinal Devices Compared to Orthopedic Cases



Source: AAOS; Various company financials; National Center for Health Statistics; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Figure 7
Sofamor Danek Group, Inc.
Market Sizes for Spinal Subsegments
($ in millions)



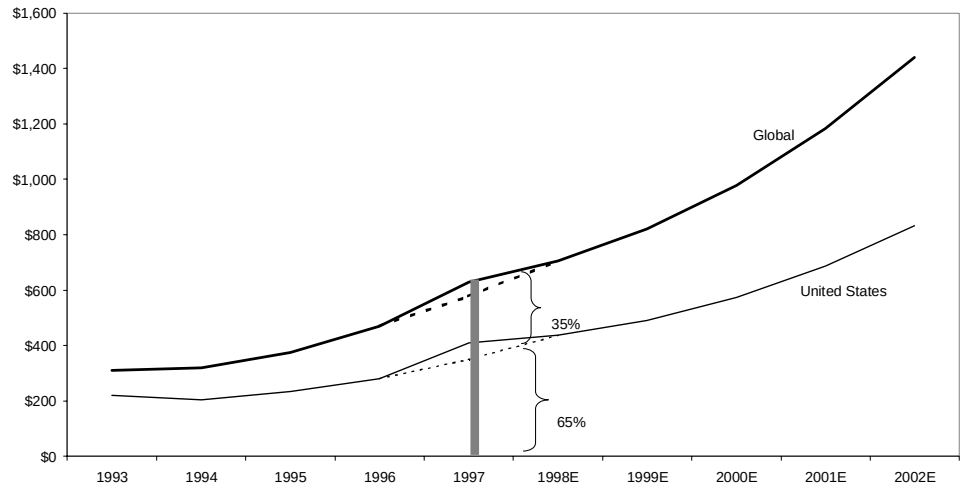
Source: Various company financials; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Core spinal implant market is growing rapidly. The global spinal implant market is by far the most-important subsegment of the spinal device market. It constitutes about two-thirds of the $900 million total spinal device market, and consequently 8% of the $8 billion orthopedics market. This equates to approximately $630 million in 1997, with about two-thirds in the United States and the remainder international. The worldwide instrument and implant market should continue to grow rapidly for the foreseeable future, reaching almost $1 billion by 2000. Figure 8, on the following page, shows the implications of our 18% compounded annual growth worldwide forecast, which compares with historical growth rates for the last five years that have ranged between 3% and 34% annual gains, averaging 21% annually (see figure 9, on the next page). The historically low 3% growth in 1994 was caused by the issues regarding potential pedicle screw product liability in the United States, as discussed earlier and in appendix F. This lower growth was more than made up for in the years since.

There are five quantitative drivers for future growth of the spinal implant market. These drivers are implant penetration in non-instrument surgery; increases in fusion rates as part of existing procedures and practices; underlying population growth; the aging of the population; and an increase in fusions related to laminectomies/discectomies (see discussion below regarding fusion cage and traditional implant growth). Figure 10 (the first of a series of figures beginning on page 15) shows the estimated relative effect of these drivers in the United States from 1997 to 2002. The strongest driver of growth, accounting for 57% of the increase, is greater use of implants in non-instrumented procedures. As illustrated in figure 11, while 95% of thoracic fusion procedures in the United States use instrumentation, less than 60% of lumbar fusions use them and even more importantly only 30% of cervical procedures do. Consequently, there is still substantial growth potential through increased cervical and lumbar use, accounting for 45% and 40%, respectively, of total fusion procedures. As overall fusion procedures have increased, the mix of procedures by region of the spine appears to have remained relatively constant (see figure 12), so this potential should remain proportional. The second most-important driver is the increased use of fusion as estimated in figure 13, accounting for 24% of the growth. Next, underlying changes in the population account for 13% of the growth, with about two-thirds of this coming from normal growth in population and one-third from increases in the proportion that are older—as dem-

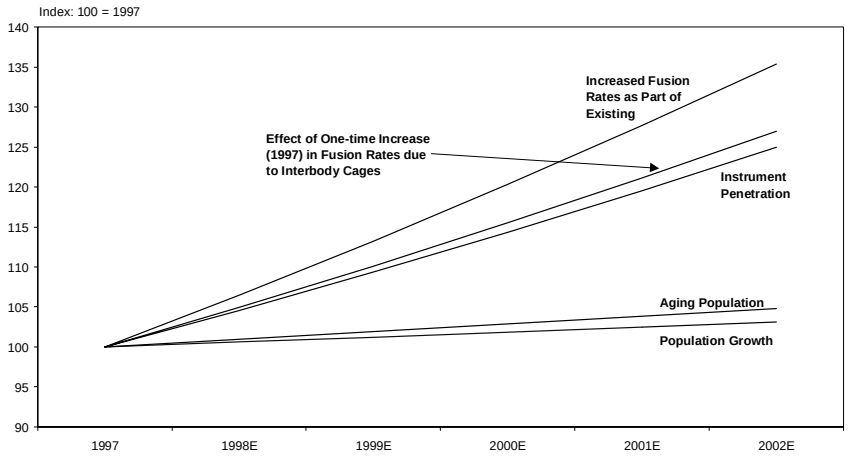
onstrated in figure 14, which shows the number of people aged 45-64. The final driver is the additional instrumentation use and procedures driven by interbody fusion cages, as discussed in more detail below. This accounts for 6% of the new growth, solely on the basis of modest increases in the current cage base-usage rate, not another step function increase as seen from 1996 to 1997 and depicted in figure 15. In summary, we have calculated potential scenarios in figure 16 that assume various rates for fusion to treat instability; penetration of implants into non-instrumented fusion procedures; and fusion rates to treat disc herniation as part of a laminectomy/discectomy. The compounded annual growth rates for these possible scenarios range from 13% to 24%, at least double-digit growth and in line with our 18% estimate.

Figure 8
Sofamor Danek Group, Inc.
Spinal Implant Market Size
(in millions)



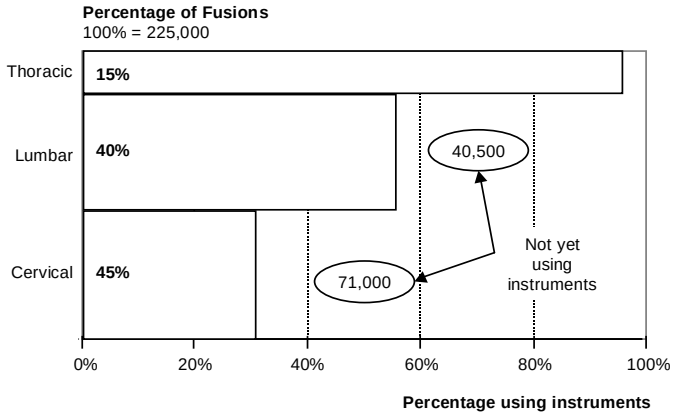
Source: Various company financials; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C.

Figure 10
Sofamor Danek Group, Inc.
Relative Importance of U.S. Spinal Implant Market Size Drivers



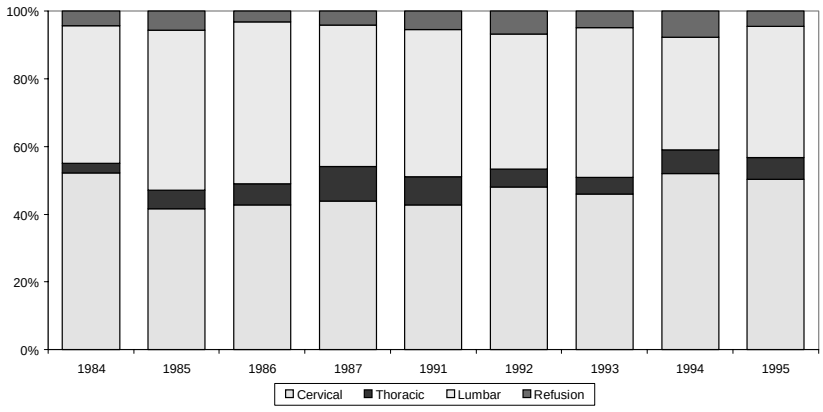
Source: SDG; William Blair & Company, L.L.C. analysis

Figure 11
Sofamor Danek Group, Inc.
Analysis of 1996 U.S. Fusion Procedures



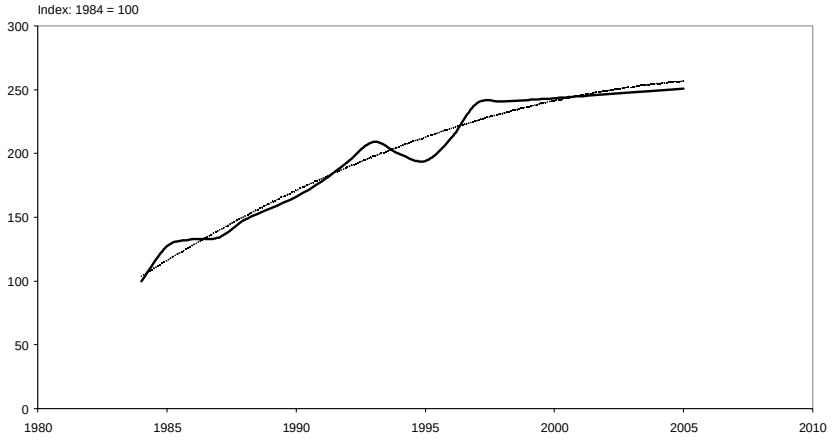
Source: SDG; William Blair & Company, L.L.C. analysis

Figure 12
Sofamor Danek Group, Inc.
U.S. Fusion Procedures



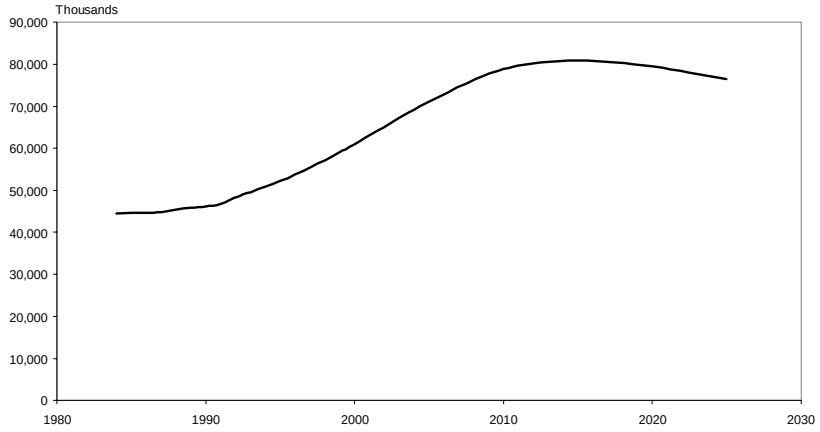
Source: NCHS; US Census; William Blair & Company, L.L.C. analysis

Figure 13
Sofamor Danek Group, Inc.
Spinal Fusion Rates



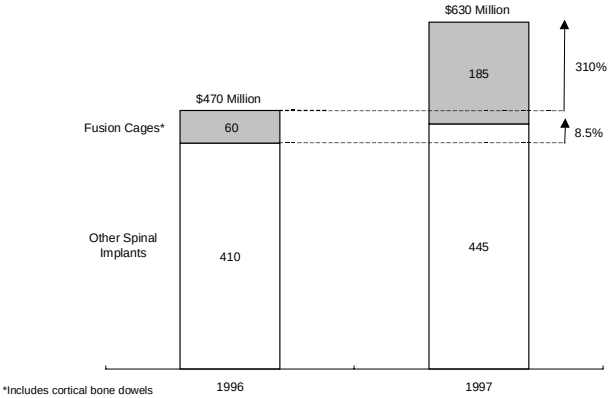
Source: Various company financials; National Center for Health Statistics; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Figure 14
Sofamor Danek Group, Inc.
Estimated U.S. Population 45-64 Years Old



Source: U.S. Census Bureau; William Blair & Company, L.L.C. analysis

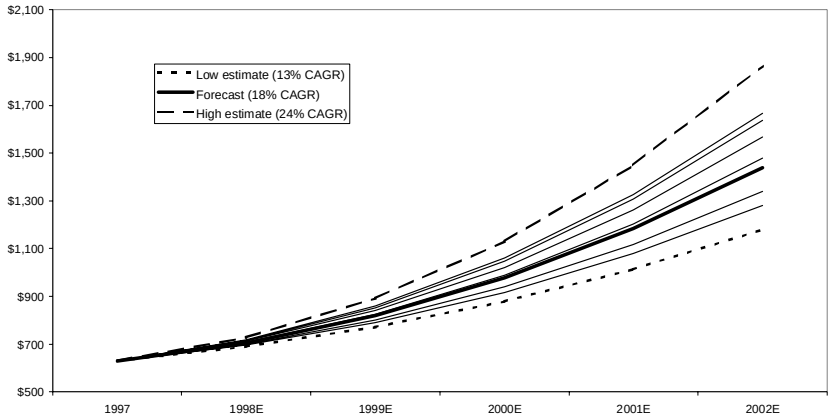
Figure 15
Sofamor Danek Group
Recent Spinal Implant Market Growth



*Includes cortical bone dowels

Source: Various company financials; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Figure 16
Sofamor Danek Group, Inc.
Spinal Implant Market Size Scenarios
(in millions)



Source: Various company financials; National Center for Health Statistics; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

The total cost and burden of spinal disorders are strong qualitative drivers of growth. As table 4 illustrates, spine conditions and injuries are common, disruptive, and costly. Businesses and government want to reduce time-off and other costs associated with spine-related disabilities, which total at least $100 billion annually worldwide for back pain alone. In addition, patients want to eliminate chronic pain and loss of function. Consequently, payors, physicians, and patients all have a vested interest and financial incentives to treat these illnesses.

Table 4
Sofamor Danek Group, Inc.
Total Effects and Costs of Spinal Conditions

- At least $100 billion total cost worldwide for back pain alone
- Most common medical complaint (back pain) – United States
- Second most common reason for being absent from work (after the common cold)
- 100 million lost work days – United States
- Most common cause of disability for under age 45 – United States
- More than 15 million spine-related visits annually to physician offices, ERs, or outpatient clinics – United States
- Four of five adults will experience significant back pain during their lives

Source: AAOS; NASS; *Spine*; New England Journal of Medicine; American Journal of Public Health; *Safety & Health*; *Business & Health*; National Center for Health Statistics; U.S. Census Bureau; Agency for Health Care Policy and Research; William Blair & Company, L.L.C. analysis

Interbody fusion cages will be a significant subsegment, but traditional implants will remain important. Recently, there has been much discussion about interbody fusion cages, which may have the potential to replace many traditional implants. However, traditional implants still have great utility, not only in long-back areas such as deformity where they are still required, but also in the larger market for the degenerative diseases, especially in multi-level fusions. As seen in figure 15, sales of traditional implants continue to grow in spite of the explosive growth of cages in 1997. Many prognosticators were expecting significantly more cannibalization than has been seen thus far. One likely explanation is that the cages are stimulating primary demand. By adding a cage implant to the surgery, the surgeons are reimbursed more. Cages probably are used in laminectomy/discectomy procedures that

previously did not involve fusion, as a preventive treatment against later surgery often needed to stabilize the spine. In addition, there is certain portion of the market that favors 360-degree fusion, which uses both interbody cages and more-traditional implants.

Image-guided Surgery Market Building, With Large Potential

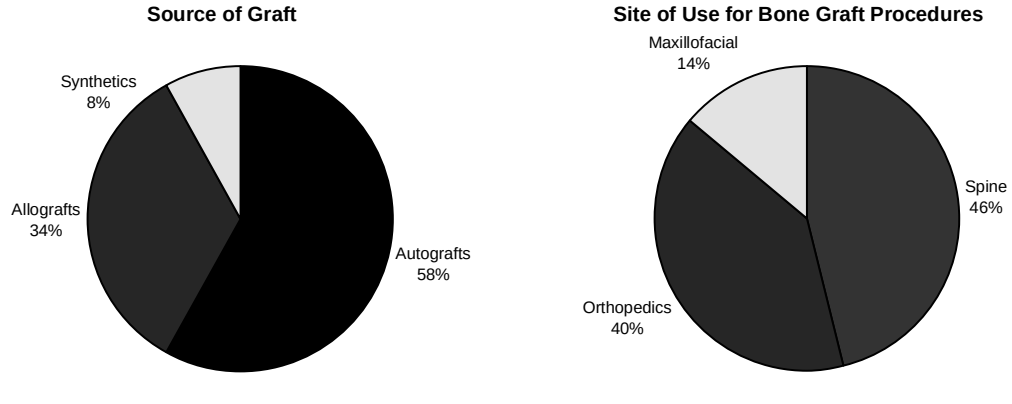
The image-guided surgery market has the greatest potential among all the spinal market subsegments, in our opinion. While it is currently only about 7% of the $900 million total spinal device market, it has the potential to be an almost-billion-dollar market, in our view. These instruments could be used in surgeries that benefit from the more-exact localization possible by this technology. Examples include surgery on the spine and cranium, as well as ears, nose, and throat; radiosurgery; total joint replacement; and complex fractures. Consequently, for inpatient surgery alone in the United States, there are 3,500 potential sites, with a total of 9,000 worldwide. In addition, larger institutions are purchasing second and third systems. At a total cost of $300,000 for an initial installation of an instrument, plus about $50,000 for each additional software package and $25,000-$30,000 yearly maintenance contract fees, the ultimate market size could be $700 million to $900 million annually.

Bone Growth Enhancers Market Also Growing Rapidly, With Substantial Potential

Bone growth enhancers are used to increase the likelihood and rate of bone growth in surgical procedures. As seen in figure 17, they are predominantly used in the spine, but also in other orthopedic procedures such as total joint replacement and maxillofacial or skull procedures. These enhancers are used in conjunction with or as a replacement for the patients' own bone or autografts and are classified into five groups: processed bone from cadavers or animals (allografts), synthetic materials, bone growth factors, electrical stimulation, and ultrasound. For the most common type of enhancer—bone graft materials—nonautograft products currently represent less than 50% of the market. In addition, many of the allograft products currently are supplied by nonprofit tissue banks. Therefore, the commercial market currently is only about $70 million, with $56 million in the United States, and is dominated by Osteotech, which has a 62% share, as shown in figure 18, on the facing page. However, the commercial market is growing more than 30% per year, due to market acceptance of proprietary processed bone products, as well as synthetic materials. If all current procedures were to use some form of enhancer, the potential global market size could be more than $600 million and growing due to increased spinal and other orthopedic procedures that require enhanced bone growth following surgery.

Figure 17
Sofamor Danek Group, Inc.
Bone Graft Market Shares

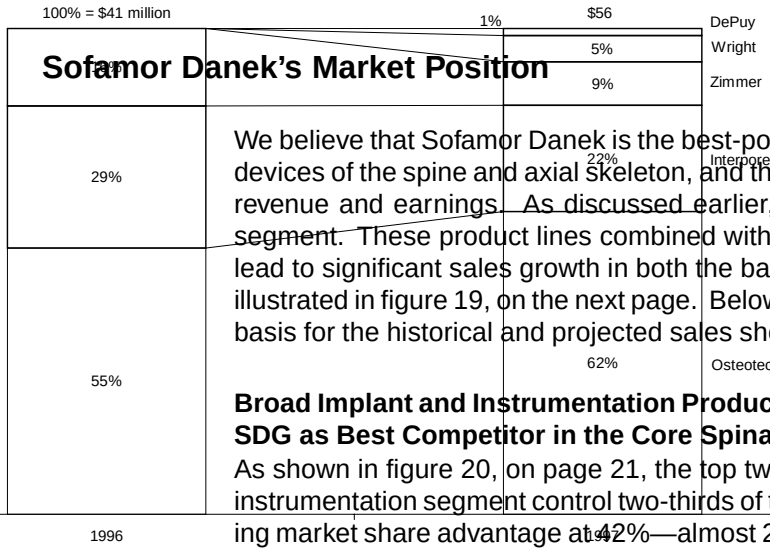
100% = 426,000 Procedures



Source: Medical Data International

Other Spinal/Cranial Markets Growing More Slowly, but Present an Opportunity
In addition to the fast-growing, potentially large markets mentioned above, the spinal market also has some other subsegments that total more than $100 million, but are expanding less than 10% per year: the cranial market for drills and titanium plates and the discectomy market (see figure 5, on page 12). While these markets are growing more slowly, they still offer worthwhile opportunities for new entrants with superior products and market access, such as those possessed by SDG.

Figure 18
Sofamor Danek Group, Inc.
Share of Commercial Graft Suppliers



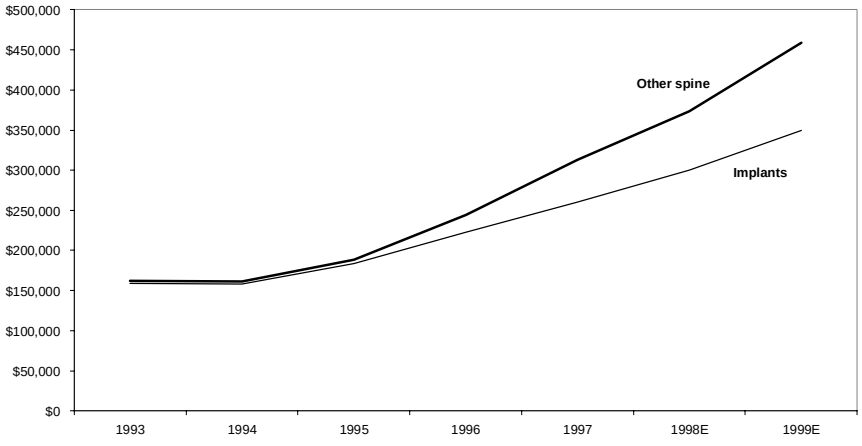
Sofamor Danek's Market Position

We believe that Sofamor Danek is the best-positioned competitor in the market for medical devices of the spine and axial skeleton, and therefore should achieve substantial growth in revenue and earnings. As discussed earlier, SDG has the broadest product line in this segment. These product lines combined with the company's strengths mentioned should lead to significant sales growth in both the base implant and the other spinal products, as illustrated in figure 19, on the next page. Below is a discussion of the products that form the basis for the historical and projected sales shown in table 5, also on the following page.

Broad Implant and Instrumentation Product Lines and a Deep R&D Pipeline Position SDG as Best Competitor in the Core Spinal Implant Segment
As shown in figure 20, on page 21, the top two competitors in the core spinal implant and instrumentation segment control two-thirds of the market, with SDG having the overwhelming market share advantage at 42%—almost 2 times the size of its next-largest competitor, the recently merged DePuy Motech/AcroMed combination. As depicted in figure 21, SDG has two well-established, extremely successful, middle- and lower-back instrument lines, TSRH® and CD™, respectively, with steady sales of about $80 million and $50 million. Each product line is the size of almost any other spine competitor's total sales. In addition, SDG continues to innovate in these established product lines. It has added the low-profile CD Horizon™ and Compact CD lines, which are less surgically intrusive for multilevel and long back procedures; TSRH Crosslink®, low-profile Crosslink® and Variable Angle Screws; connectors to allow for combinations of parts from all the various SDG systems; and the Sofamor

Danek Multi-Axial Screw for significantly easier positioning during surgery. The company also has developed other middle- and lower-back systems, such as the ALPHA™ posterior and Liberty™ anterior spinal systems and the recently acquired Colorado, a maker of spinal systems in Europe. In the cervical spine area, SDG has had a phenomenal success with the Orion™ anterior cervical plate system as also illustrated in figure 21. SDG is continuing to innovate by developing the new ACPii anterior cervical plate system, and, with the University of Florida Tissue Bank and Regeneration Technologies, it has developed the Cornerstone™ bone block spacers for cervical use. Lastly, while SDG has not yet received FDA clearance for one of the most-popular spinal implant products—interbody cages—for spinal fusion, it is still best-positioned, in our opinion, for eventual leadership. Since the company is not yet approved for cages other than the MD allograft bone dowels, it currently only has 7% of the U.S. market, as shown in figure 22, on the facing page, presenting a large upside opportunity due to its pipeline. In addition to the allograft bone dowels, it has the most robust R&D pipeline, including its metal Novus cage, a cage made of Hedrocel™ (an open-pore tantalum material), and the carbon-fiber cage acquired from MAN. Also, it is developing cages that combine rhBMP-2, a bone growth factor, within the structure of a synthetic (e.g., titanium or Hedrocel™) or biologic structure (e.g., bone dowel). Below is a more comprehensive discussion of these product lines.

Figure 19
Sofamor Danek Group, Inc.
Implant Plus Other Spinal Products Revenue
(in thousands)



Source: Various company financials; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Table 5
Sofamor Danek Group, Inc.
Product Line Sales

	1992	1993	1994	1995	1996	1997	1998E	1999E
Other Spinal Implants*	6	17	25	38	61	88	108	132
TSRH**	63	86	79	81	81	75	80	80
ORION	0	0	5	15	24	34	45	60
StealthStation	0	0	0	0	8	36	48	60
CD**	45	55	49	49	56	53	50	50
MD I & II	0	0	0	0	0	10	18	27
MedNext	0	0	0	0	3	4	4	5
MED System	0	0	0	0	1	2	3	4
DANEK	6	2	0	0	0	0	0	0
Other***	2	2	4	5	10	11	18	40
Total	121	162	162	189	245	313	374	459

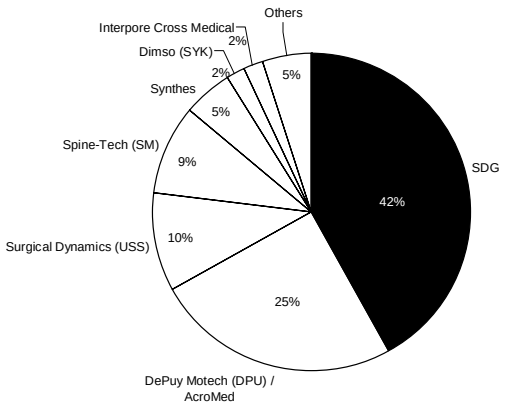
*Includes new implant systems such as Colorado; certain product line extensions for TSRH and CD; and non-allograft interbody fusion cages

**Does not include certain product line extensions

***Includes products not elsewhere classified such as TiMesh

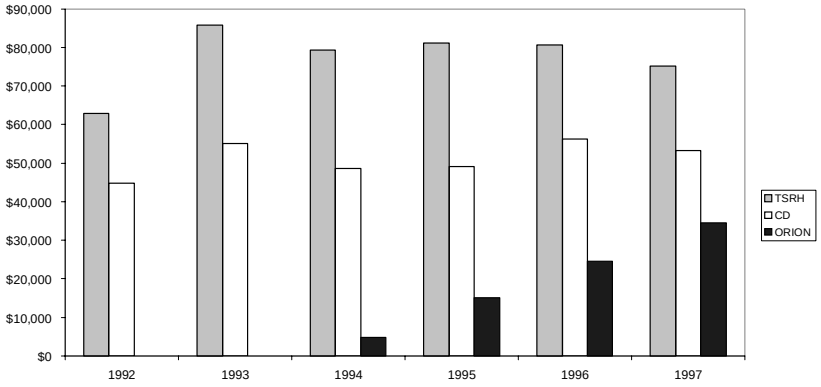
Source: SDG financials; interviews; MDI; MarketLine; Frost & Sullivan; Dun & Bradstreet; Theta; William Blair & Company, L.L.C. analysis

Figure 20
Sofamor Danek Group, Inc.
Global Implant Market Shares



Source: Various company financials; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Figure 21
Sofamor Danek Group, Inc.
Sales of Key Established Product Lines*
(in thousands)

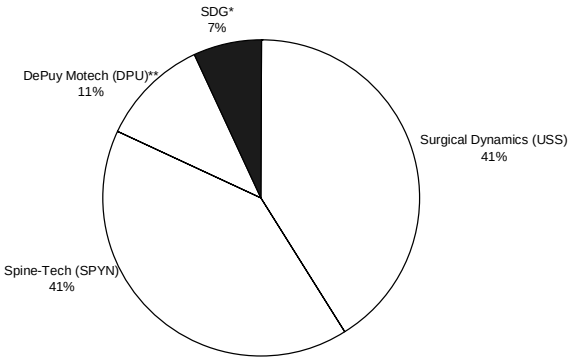


*Does not include some product line extensions

Source: SDG financials; William Blair & Company, L.L.C. analysis

Figure 22
Sofamor Danek Group
U.S. Fusion Cage Market

100% = $135 Million



* Includes cortical bone dowels
** Includes Surgical Titanium Mesh

Source: MDI and William Blair & Company, L.L.C. analysis

Sofamor Danek's Major, Traditional Low- and Mid-back Fixation Products

TSRH®. In 1989, SDG launched the TSRH® system, developed at the Texas Scottish Rite Hospital. This system is used predominantly to treat deformities of the spine, such as scoliosis, which helps explain its stable sales. There are special versions of the system to treat pediatric cases and for other indications such as for adult lumbar surgery. In addition, SDG has continued to innovate the system, i.e., adding variable-angle screws and top-tightening bolts that allow for much greater flexibility in placing and tightening the screws.

CD™. In 1984, SDG launched the Cotrel-Dubousset (CD™) system, developed by Dr. Yves Paul Cotrel and Professor Jean Dubousset. The original system was designed to treat deformities and fractures of the lumbar and thoracic sections of the spine. As with TSRH®, the company has continued to improve the CD™ system, introducing the Compact CD™ or CCD™ system for degenerative diseases of the lumbar and sacral spine and the CD Horizon™ system, which combines new types of hooks and screws with components of other SDG systems to create a flexible system that can treat a variety of spinal conditions.

Sofamor Danek's Major Cervical Systems

Orion™. In 1994, SDG launched the Orion™ Anterior Cervical Plate System to stabilize the anterior cervical spine for fusion procedures on patients with degenerative disc diseases, fractures, or tumors. The system was developed with the assistance of Dr. Gary L. Lowery.

Cornerstone™. Later this year, SDG will launch Cornerstone™ bone block spacers, a product line co-developed with Regeneration Technologies, a recent spinoff from the University of Florida Tissue Bank. These products comprise 20-30 allograft bone spacers in the various shapes and sizes to replace 80% of the manually "whittled" autograft bone. In addition, SDG will launch specialized MedNext burs to rapidly customize these products when needed.

Sofamor Danek's Major Interbody (Fusion) Cages

Novus® LC. The Novus® LC is a metal threaded cylindrical cage. The FDA reviewed the premarket approval (PMA) for the Novus® LC on December 11. It was not approved, however, because there were only two years worth of follow-up data for 33% of the patients in the study. Both the BAK and Ray cages required two-year data to receive approval. SDG had believed that it would not need the full two years on all patients, because it used an approach to its clinical trial preferred by the FDA over that used by Spine-Tech and Surgical Dynamics. The company conducted a prospective trial where patients were randomly assigned one of two treatments, either the Novus® LC or the control. Both competitors used literature controls. In this case, the length of follow-up time was more important to the FDA advisory committee than the type of controls. Although we still believe that SDG will get approval, it must wait until the two-year data is available for the full complement of patients in the trial. This would mean a probable first half 1999 clearance.

MD-I and MD-II. Prior to approval, SDG is supplying cortical bone dowel allografts supplied under an exclusive agreement by the University of Florida Tissue Bank. Providing these products allows SDG to develop its market presence in this segment before launch of the Novus® LC. These natural products are available both smooth (MD-I) and threaded (MD-II). SDG has been providing these for about one year—they do not require FDA approval because they are human tissue. Overall supply of these products is restricted due to limited donations; thus supply limits sales, not demand. In the end, a market likely will exist for both standard cages, as well as the natural cortical bone dowels.

Additional horizontal cage products. Recently, SDG purchased the assets related to a carbon-fiber fusion device produced by MAN Ceramics. This carbon-fiber device has unique features such as transparency to most types of imaging, and it has a modulus or elasticity closer to bone than does titanium. The device was designed by Dr. Rudolph Bertagnoli, a leading German spine surgeon, and more than 1,400 have been used in Europe in the last five years. In addition to this device, SDG is developing a tapered device made from Hedrocel™, which has an open-pore tantalum conducive to bone in-growth. The taper of the device helps to contribute to the proper lordosis, and the pores allow for a combined use as a delivery device for other materials, such as bone morphogenetic proteins.

Cages combined with BMPs (see section on bone growth enhancers below). As mentioned, the Hedrocel™ cage can be filled with rhBMP-2 to promote bone in-growth faster than with bone graft alone. In addition, even a Novus® cage and the MD cortical bone dowels can be filled with the BMP. Therefore, SDG will have both synthetic and natural products combined with growth factors, in addition to implants alone. Currently, SDG has 12-month data on its tapered or lordotic Novus® cage and has initiated a pilot trial using the MD threaded bone dowels. It will apply to the FDA for a combination metal (Novus® TC) and BMP product, with a likely approval in 2001; however, it has agreed with the FDA to only sell rhBMP-2 as part of this combination. The combined threaded bone dowel and rhBMP-2 product likely will be approved one or two years later, and SDG will not be able to bundle the two for sale because the bone dowel is human tissue. Therefore, rhBMP-2 will be available alone. Determining the ultimate benefit of these combinations will have to wait until the final results of the ongoing clinical trials, but the possibilities of leap-frogging the competition are exciting.

Sofamor Danek's Prosthetic Discs

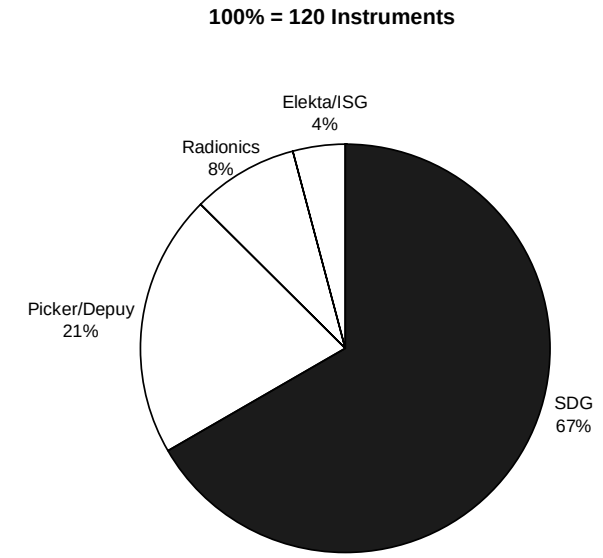
Sofamor Danek's major prosthetic disc developmental product is the articulated porcelain disc. The company actively is investigating and developing various product designs for prosthetic discs to replace a human disc, thus trying to preserve its functions. The leading candidate in its pipeline is an articulated porcelain disc. At this point, this product would require a PMA prior to marketing in the United States.

Additional Complementary Product Lines Targeted at the Same Customer Base Create More Growth Opportunities

To promote growth and enhance its leading position, SDG continues to add new types of products for the same target-customer segments. Building on the core spinal implant segment, SDG has established positions in four other related business: image-guided surgery, bone growth enhancers, discectomy, and cranial. These products are sold to the same target spine-specialist customers—orthopedic surgeons and neurosurgeons. In the fast-growing image-guided surgery (IGS) market, SDG has achieved by far the highest market share in the United States after its 1996 acquisition of Surgical Navigation Technologies (see figure 23). As previously mentioned, the company has developed alliances with Vista Medical Technologies and GE Medical Systems to add other IGS product line extensions. SDG is approaching the other fast-growing segment, the bone growth enhancer market, primarily through a collaboration and licensing agreement with Genetics Institute for rhBMP-2, which has been shown to stimulate bone growth more rapidly. Before year's end, the company will begin to market a new product derived from donated human bone and developed in conjunction with the University of Florida Tissue Bank and Regeneration Technologies, Osteofil™ injectable bone paste. For the slower-growing discectomy market, SDG successfully has launched its MED Microendoscopic System, the only midline endoscopic system on the market, to complement its "open" Danekscope for "open" microdiscectomy. Sales are increasing rapidly from a small base and should continue to capture share of the overall discectomy market, as illustrated in figure 24. SDG's position in IGS has allowed it to enter the cranial market as well. To complement the StealthStation in that market, SDG has acquired the TiMesh™ complete neuro-craniofacial plate, screw, and mesh system, as well as the MedNext® high-speed bone dissecting system, with the antikick feature preferred by

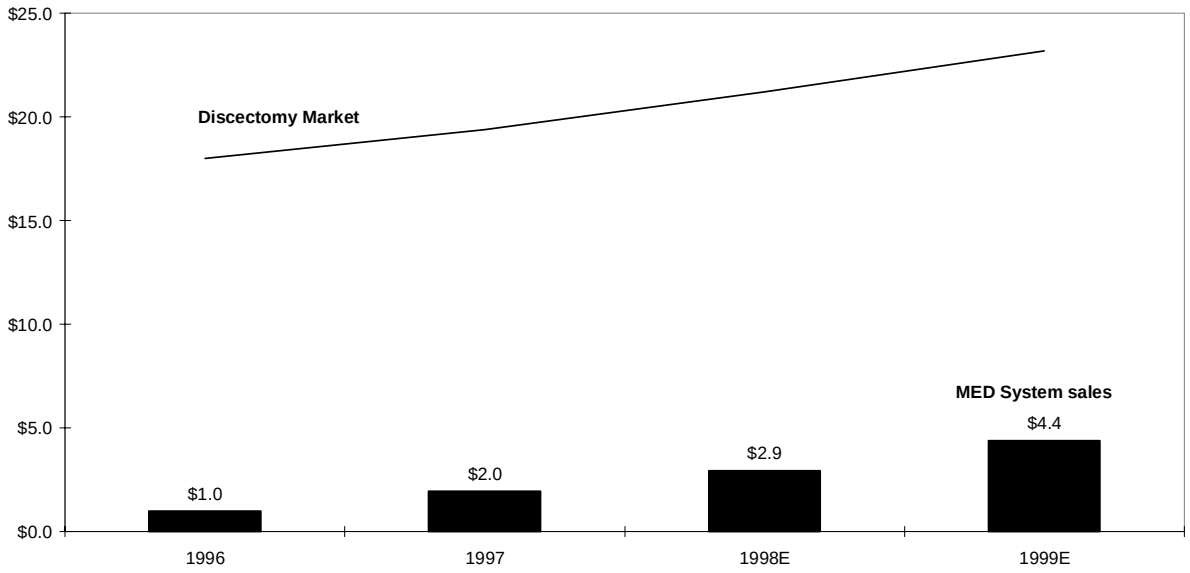
surgeons. As figure 19 shows, the result of successfully adding these complementary product lines has been continued accelerated growth beyond that produced by implants. Details of the IGS product line are discussed below.

Figure 23
Sofamor Danek Group
Frameless IGS Systems Placed in the United States in 1997



Source: MDI and William Blair & Company, L.L.C. estimates

Figure 24
Sofamor Danek Group, Inc.
U.S. Discectomy Market Size and MED System Sales
(in millions)



Source: Various company financials; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Image-guided Surgery

SDG currently leads the image-guided surgery market with at least a 50% market share worldwide and two-thirds of the 120 placements in the United States (see figure 23). In the short term, this $60 million market should expand faster than 30% per year. These systems are sold as capital equipment to institutions such as hospitals. Therefore, there is often a yearly budgeting cycle and sometimes a trial period competing against other instruments. However, while hospital administrators are involved, the surgeons are still the ultimate decision-maker, thus providing SDG with a visible advantage due to their strong relationship to the surgeons. We believe that sales from this product line should continue to increase and significantly contribute to the overall performance of SDG, and as depicted in figure 25, on the next page, overtake the CD system as percentage of total revenue by 1999.

StealthStation™. Surgical Navigation Technologies (SNT), located in Broomfield, Colorado, is the maker of the StealthStation™ frameless IGS medical workstation, which received 510(k) approval for cranial and spinal applications in January 1996. In April 1996, SDG acquired SNT, following its 19.5% investment in SNT in March 1995, through which SDG gained the exclusive worldwide rights (except in South Korea) to manufacture and distribute SNT's products for spinal and neurological indications. In 1997, SNT was by far the market share leader in IGS systems with 67% of 1997 U.S. instrument placements, competing against DePuy Motech/AcroMed in an alliance with Picker, as well as Radionics and the pioneer, Elekta (see figure 16).

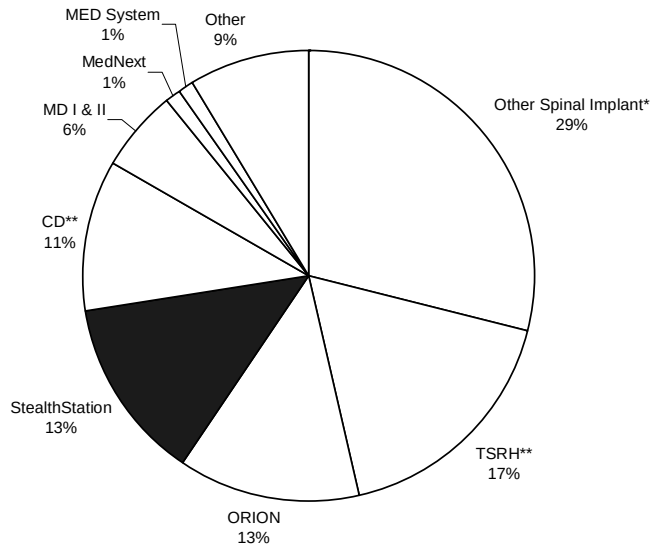
The instrument comprises the workstation, the frameless tracking system, specialty software packages, and some surgical tools. The base system costs about $260,000, with the case planning software costing $45,000 and the specialty software priced at about $50,000 (e.g., the cranial package is $56,000). Currently, SDG has packages for the spine; cranium; and ear, nose, and throat, with radiosurgery and total joint replacement in development. In addition, the company may develop a complex fracture package. Over time, it anticipates that only one-third of revenue from this business will come from capital equipment sales, with the remaining two-thirds split between software and a profitable service business.

Recent product enhancements through alliances. In December 1997, SDG obtained an exclusive worldwide alliance with Vista Medical Technologies for the development and distribution of Vista's 3D head-mounted display and image acquisition technology for orthopedic (spinal), neurological, and otolaryngology indications in conjunction with the StealthStation™. It will be used for image-guided surgery, as well as microscopy and endoscopy. This is a five-year agreement with subsequent two-year renewals possible. On December 9, 1997, Vista Medical received 510(k) approval for use of its StereoSite 3D head-mounted display system, including the Informatix Software 1.0, in head, neck, and spine microsurgery.

In March 1998, the company signed an exclusive alliance with GE Medical Systems to market GE's Signa SP IntraOperative Magnetic Resonance System™ in the United States, which now will be part of its StealthStation™ Treatment Guidance Platform. The Signa SP system allows for real-time imaging during surgery.

Figure 25
Sofamor Danek Group, Inc.
SDG 1999 Product Line Sales

100% = $459 million



*Includes cages, new implants (e.g., Colorado), and TSRH and CD product line extensions
**Does not include all product line extensions

Source: SDG financials; interviews; William Blair & Company, L.L.C. analysis

Bone growth Enhancers

RhBMP-2. In 1995, SDG began a collaboration with the Genetics Institute (GI)—now a subsidiary of American Home Products—to develop exclusively the North American spinal market for rhBMP-2, the second form of recombinant human (rh) bone morphogenetic protein (BMP). For this right, SDG agreed to pay $50 million over a four-year period. GI will manufacture the product exclusively for SDG. In 1997, SDG completed a successful small human clinical that combined rhBMP-2 with a lordotic interbody fusion cage. The product was implanted into 11 patients, with 10 patients achieving fusion in 3 months and 1 patient in 6 months; the typical time for fusion is 18 months. As mentioned, SDG has the ability to combine rhBMP-2 with a variety of cage devices, including those made from titanium, carbon-fiber, allograft bone dowels, and the Hedrocel™ porous tantalum material.

Osteofil™ injectable bone paste. In conjunction with Regeneration Technologies, SDG will launch this allograft product later this year. It is similar to a demineralized bone (DBM) putty, but is made with human collagen instead of glycerol. Consequently, it contains a higher concentration of DBM, but must first be warmed to decrease its viscosity prior to injection. SDG is targeting its use as a backfill to harvested iliac crest autograft, because it believes that the iliac crest autograft promotes a better spinal fusion. As the processing yields are greater for this product versus the cortical bone dowels, supply should not be an issue.

Discectomy

Sofamor Danek's major discectomy product is the MED™ Microendoscopic Discectomy System. SDG is the only company to currently offer a midline, microendoscopic system. The system has been used in almost 2,000 procedures to date, with a 93% success rate, versus 80% for open approaches, 74% for other endoscopic procedures, and 62%-69% success for all other approaches. In addition, table 6 shows these and other benefits derived from the system, including a significantly shorter length of stay in the hospital, fewer complication rates, and lower blood loss. There are more than 150 surgeons trained on this system and 35 hospitals using it. The system costs $20,000 to $60,000, plus there is a $1,000 disposable scope used for each procedure. The current average total cost of a discectomy is $10,000 to $15,000, including surgeon and operating-room time, but not including the inpatient hospital stay. While using the MED™ system equates to a $500-$800 higher surgical cost, which is more than compensated for by an average length of stay in the hospital that is more than one day shorter, at $500 to $1,000 per day.

Table 6
Sofamor Danek Group, Inc.
Comparison of MED System to Open Microdiscectomy

	MED System	Open Microdiscectomy
Location	Most often outpatient	Inpatient
Average hospital length of stay (LOS)	11 hours	44 hours
Complication rate	4%	8%
Estimated blood loss	21 cc	45 cc
Average operating room time	101 minutes	90 minutes
Additional cost per operation*	$500-800	

***Does not include inpatient cost of longer LOS for Open Microdiscectomy $500-1,000 per day**

Source: PhDx; SDG; William Blair & Company, L.L.C. analysis

Cranial Surgery

Sofamor Danek's major cranial products are the TiMesh® surgical mesh and MedNext bone dissecting drill system. The company's entry into the IGS market provided it excellent access to a broader range of neurosurgeons, not just those who operate on the spine, but those who operate on and in the cranium as well. To add to the targeting and navigational capabilities of the StealthStation™, SDG added cranial repair, with the TiMesh® cranial, plate, screw, and mesh system, and cranial access, with the MedNext® high-speed pneumatic bone dissecting drill system. The TiMesh® system features the patented Plate Holder-ID Tag for easier handling and product traceability and "high torque" screws designed to reduce breakage significantly. The MedNext® system has the patented and highly regarded antikick mechanism to eliminate the kick previously experienced with start-up. The drill also can be used in microendoscopic discectomy procedures. Currently, in the surgical drill market, Midas Rex dominates, and Leibinger, a division of Howmedica (a subsidiary of Pfizer), and Synthes have the major positions selling titanium mesh.

Growth Opportunities

In summary, we believe that Sofamor Danek will be able to sustain growth using three powerful levers: 1) continued dominance of the spinal implant and instrumentation market, which should grow 18% annually; 2) growth in sales to the same target customers of new types of products, such as image-guided surgery instruments and bone growth enhancers—markets that should expand more than 30% per year; and 3) international growth estimated at 23%-25% per year.

SDG should continue to lead the core spinal implant market, which is growing almost 20% per year, and likely gain share due its strong interbody fusion cage pipeline.

The core spinal device segment—implants and instrumentation—should expand to almost $1 billion by 2000. The factors contributing to this growth are: a need to reduce the total cost and overall burden of back conditions and injuries, which currently approaches $100 billion worldwide; the aging of the population, which then is likely to suffer spinal difficulties; instruments that allow for and enhance the results of surgical interventions to address theses difficulties; a likely rise rate of spinal fusions per member of the population; and the use of implants in procedures that are currently not instrumented.

SDG should continue to command the strongly growing, $630 million worldwide spinal implant market, building on its current 42% share. Its leadership is supported by a loyal customer base of surgeons for whom it has assembled the broadest complementary product line of any competitor and to whom it provides the most comprehensive package of physician- and patient-support services, including the manufacture of custom implants, practice-management tools, coding assistance for billing and reimbursement, cost-justification analysis for capital equipment, and automated outcomes tools. SDG's two well-established, extremely successful mid- and lower-back instrument lines, TSRH® and CD™, should maintain steady sales of about $80 million and $50 million, respectively, as SDG continues to improve these and newer product lines, such as the ALPHA™ posterior and Liberty™ anterior spinal systems and the recently acquired Colorado spinal systems. In the cervical spine area, SDG should maintain its success with the Orion™ anterior cervical plate system and add sales with new metal plate systems, as well as its new Cornerstone™ bone spacer system. Lastly, SDG should see tremendous upside potential with its interbody fusion cage portfolio, although most of this growth will appear after 1999, as the first U.S. clearance likely will not occur until midyear.

Interbody fusion cage conclusion: SDG should lead in this market segment. While SDG did not receive FDA approval for the Novus® cage, based predominantly on the need for more follow-up data, it has the fullest pipeline and product range. As discussed, its product pipeline includes a standard horizontal titanium cylinder, as well as smooth and threaded cortical bone dowels; carbon fiber and lordotic titanium cylinders; and the novel, lordotic Hedrocel™ interbody cage. Lastly, by combining members of its cage portfolio with the bone growth factor rhBMP-2, SDG has the possibility to revolutionize these products and their performance through faster, higher-quality fusion.

We believe there is tremendous upside potential once SDG's cage products begin to penetrate the U.S. market. Recall that fusion cages currently are growing at a much faster rate than other spinal implants as shown in figure 15. However, SDG's implant revenue still is growing well despite this, even as its overall implant share declines (see figure 26) because it cannot participate fully in the U.S. market, which is now the dominant market for cages. Globally, there are several competitors for cages, however, in the United States there are only two approved products, the BAK cage from Sulzer Spine-Tech and the RayCage from Surgical Dynamics. Therefore, as one would expect, the approved products have the dominant market shares shown in figure 22. This situation should

reverse, creating great upside potential once SDG begins to receive FDA clearance in the United States for its various products, likely starting in 2000 for the Novus® LC, followed by the Novus® LT and rhBMP-2 combination in 2001, and cortical bone dowel and rhBMP-2 combination in 2002 or 2003. In the meantime, SDG still shares in the U.S. market through its sales of the limited-supply MD cortical bone dowels, which should generate at least the $18 million of sales in 1998.

Figure 26
Sofamor Danek Group, Inc.
Implant Market Share Versus Revenue
(in thousands)

Source: Various company financials; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

By adding new types of products for the same target-customer segments, SDG is creating more growth opportunities.

By building on its core spinal implant segment, SDG has established positions in other growth businesses, such as image-guided surgery (IGS) and bone growth enhancers (BGE), focused toward its target customers, the spine specialists—orthopedic spine surgeons and neurosurgeons. Combined, these markets are currently less than $300 million, but have subsegments such as IGS and BGE that are expanding more than 30% per year. In the IGS market, SDG has achieved by far the highest market share in the United States, at 67%, and has developed alliances with Vista Medical Technologies and GE Medical Systems to add other IGS product line extensions. In the BGE market, SDG achieved a collaboration and licensing agreement with the Genetics Institute for rhBMP-2, a growth factor that stimulates bone growth. It also has developed, in conjunction with the University of Florida Tissue Bank and Regeneration Technologies, a new product derived from donated human bone, Osteofil™ injectable bone paste. In addition to its innovative IGS and BGE products, SDG has innovative products, such as the MedNext™ drill, TiMesh® titanium mesh, and the MED™ Microendoscopic Discectomy system, that should capture and increase share in other, albeit slower-growing, spinal markets.

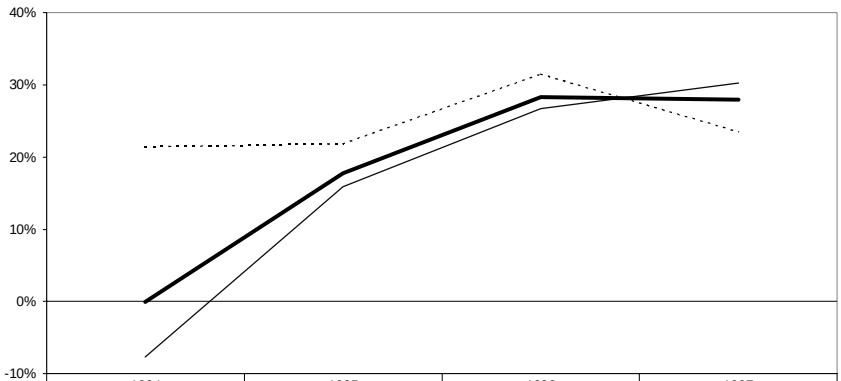
SDG's strengths outside the United States should lead to international sales growth greater than 20%.

SDG has more than $100 million in sales outside the United States. This makes its international sales greater than the total spinal implant sales of all but its largest competitor (see figure 20, on page 21). We are not surprised given the international strength of Sofamor prior to the merger with Danek. In fact, in the top five markets in Europe—Germany, France,

the United Kingdom, Italy, and Spain—SDG is the spinal implant market share leader in four, save Germany. The international strength is not only driven by SDG's broad, high-quality product line, but also its 200 independent reps outside the United States in countries where SDG has its own affiliates (refer to table 3, on page 11). In addition, SDG has stocking distributors in approximately 56 other countries.

To illustrate the value of SDG's international strength to its overall growth, note that since 1993, SDG's international sales have increased more than 21% each year as shown in figure 27. As long as this growth rate is maintained—which we believe SDG should exceed—SDG's overall sales would continue to increase, even if the United States suffered a significant slowdown or decline in growth as depicted in figure 28. Thus, this international strength not only contributes substantially to the company's growth, but also acts as a strong hedge to the faster but more-volatile U.S. growth. We estimate that SDG's international sales will increase 23%-25% per year, with fastest growth in the Pacific Rim, Europe by double digits, followed by other slower-growing markets such as Latin America.

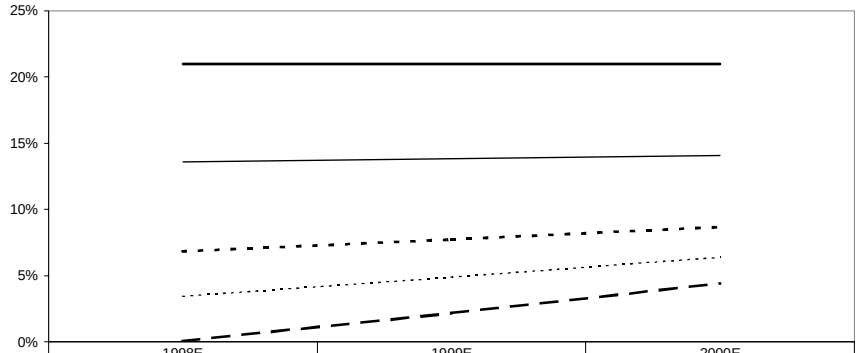
Figure 27
Sofamor Danek Group, Inc.
Geographic Annual Growth Rates



	1994	1995	1996	1997
US	-0.076399448	0.159276018	0.266978923	0.302526186
ROW	0.214060228	0.218323587	0.3152	0.234793187
Total	-0.00058909	0.177997528	0.282791186	0.279754601

Source: SDG financials; William Blair & Company, L.L.C. analysis

Figure 28
Sofamor Danek Group, Inc.
Benefit of SDG's International Position



	1998E	1999E	2000E
ROW	0.21	0.21	0.21
U.S. -10%	0.000559284	0.02160872	0.044034157
U.S. -5%	0.034340045	0.04866335	0.063842687
U.S. 0%	0.068120805	0.077169337	0.08668544
U.S. 10%	0.135682327	0.138017335	0.140422034

Source: SDG financials; William Blair & Company, L.L.C. analysis

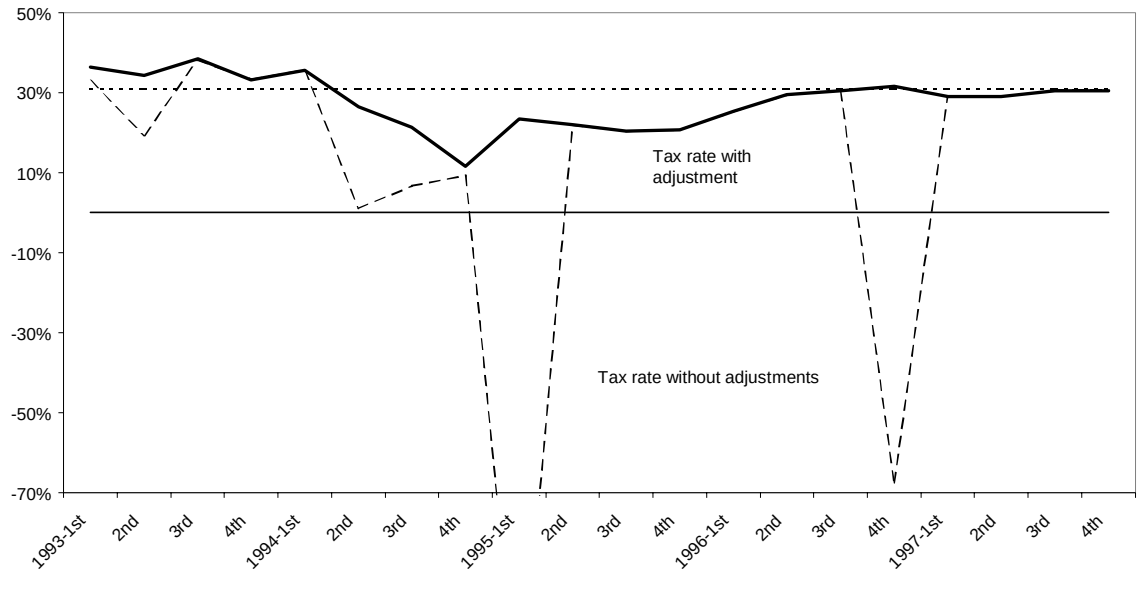
Financials

Operating Results and Forecast

Revenue. We believe that SDG's revenue and profit growth should continue to be strong. Over the past five years, SDG has experienced about 20% annual revenue growth, and this approximate rate should continue through at least 1999, as seen in figure 3, on page 8, and the income statement in table 7. While core spinal implant product sales should contribute substantially to this growth, the complementary products should begin their revenue expansion, especially the surgical systems such as the StealthStation™, MedNext™, and MED™ system, as shown in figure 19 and table 5 on page 20.

Expenses. Over the last five years, there have been decreases as percentages of sales in cost of goods (COGS) and research and development expense, with volume rising and increases in selling, general, and administrative expense, as the company built its own overseas infrastructure in key markets. We anticipate a reversal of several of these trends, with SG&A as a percentage of sales declining from 46.5% to 44.4%, as SDG begins to leverage this infrastructure. However, we estimate that COGS should increase from 18.6% to 19.6% by 1999, as capital equipment, such as the StealthStation™, makes up more of the product mix. Research and development should remain flat. This expense structure should lead to an improved operating income of approximately 30% (see figure 4, on page 11). The single most important nonoperating expense for SDG is taxes. This rate historically has been difficult to estimate due to one-time charges and foreign-subsidiary tax consequences. However, as figure 29 shows, by eliminating one-time charges, we estimate that an effective rate of 31% should approximate the likely tax expense for 1998, rising to 32% in 1999, and gradually rising by less than 1% increments in later years.

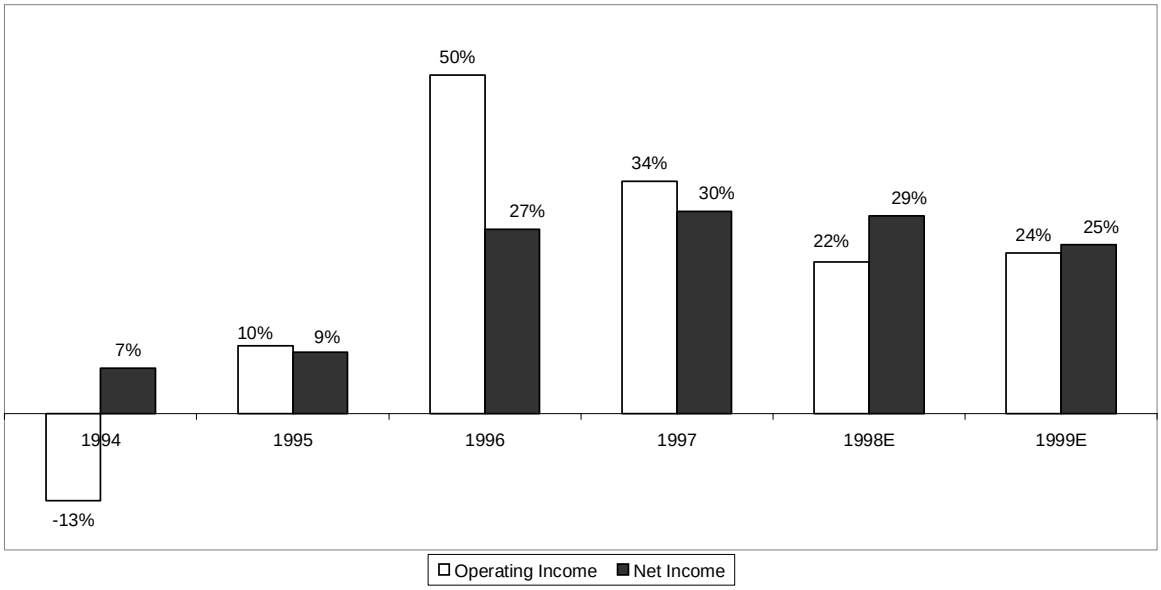
Figure 29
Sofamor Danek Group, Inc.
Historical Tax Rate



Source: SDG financials; William Blair & Company, L.L.C. analysis

Net income. As figure 30 illustrates, the net result of the expected revenue growth and expense structure is an average operating income growth of approximately 21% and net income growth of 22%. This should result in future diluted EPS growth of 22%, on par with the historical average as shown in figure 31.

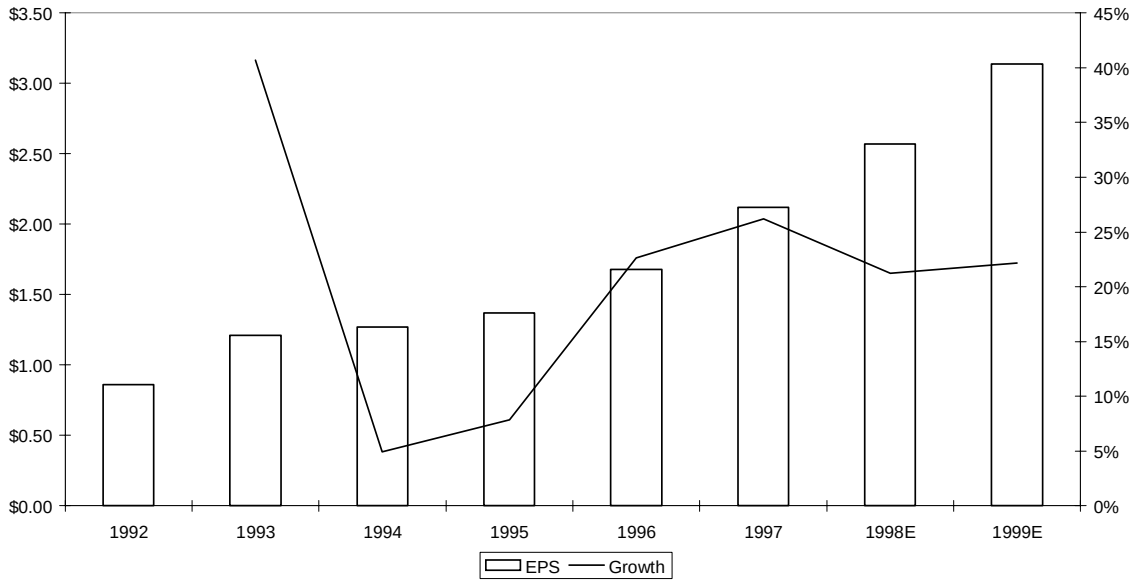
Figure 30
Sofamor Danek Group, Inc.
Operating and Net Income Growth*



*Adjusted for one-time charges

Source: SDG financials; William Blair & Company, L.L.C. analysis

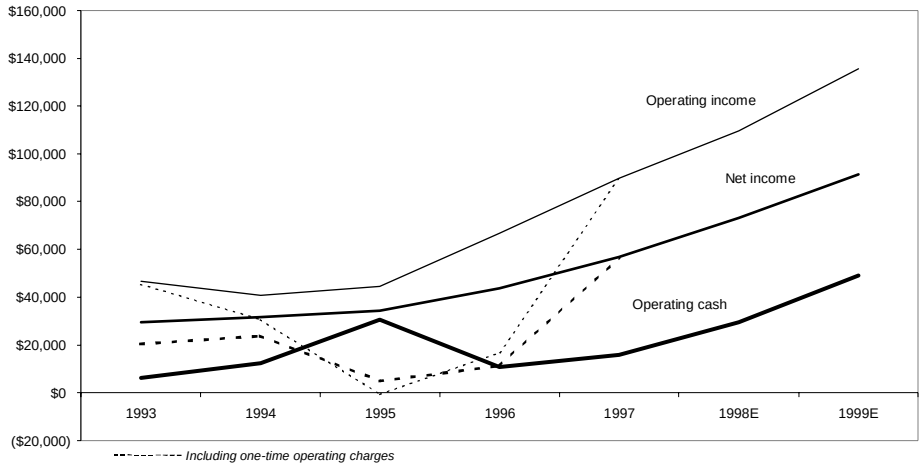
Figure 31
Sofamor Danek Group, Inc.
EPS Growth*



*Adjusted for one-time charges
Source: SDG financials; William Blair & Company, L.L.C. analysis

Cash flow. Operating cash flow also should continue to be strong and could have significant upside depending on SDG's necessary level of future investment. Figure 32 shows this development of positive operating cash flow from 1993 to 1999. It also illustrates that while operating and net income declined in 1995 and 1996 due to one-time charges, operating cash continued to be significantly positive, as these one-time charges were taken to represent SDG's financial situation conservatively. In 1995, SDG expensed the entire stream of milestone payments to Genetics Institute for licensing rhBMP-2, even though the cash disbursements would occur over a four-year period. Then in 1996, SDG took a $50 million charge to cover potential costs associated with pedicle screw litigation, again with any cash payouts to occur later (for more information, see appendix F). Obviously, these charges also helped reduce its current tax liabilities, thereby increasing net cash. As table 8 indicates, we believe that SDG will be generating close to $50 million in cash per year from operations by 1999, which combined with its strong balance sheet, gives it the capability and flexibility to acquire, license, or develop additional product lines necessary to maintain its growth.

Figure 32
Sofamor Danek Group, Inc.
Financial Performance
(in millions)



Source: SDG financials; William Blair & Company, L.L.C.

Recent Developments in Capitalization

Buyout of SOFYC, S.A. At the end of January 1998, SDG agreed to purchase SOFYC, S.A., the personal holding company of the Cotrel family, founders of Sofamor. This holding company owned 14% of SDG. To buy out the 3,337,272 shares owned by SOFYC, SDG exchanged 2,806,080 privately placed shares and approximately $2 million in cash. This resulted in 531,192 fewer shares of common stock outstanding.

Secondary offering. SDG also agreed to a secondary offering of 1.6 million shares on behalf of the SOFYC holders, plus an additional 1.2 million on behalf of SDG itself, with an overallotment option of 420,000 shares granted to the underwriters. This offering was priced at $71 per share. The company used roughly $42.7 million from the offering to pay off outstanding borrowings under its U.S. revolving line of credit. The remaining proceeds will be used for general corporate purposes.

Balance sheet. The results of these capitalization changes are an improvement in an already strong balance sheet, displayed in table 9. In addition to the $50 million in cash SDG will be generating, it will have more than $100 million in cash or equivalents by 1999 on its balance sheet to make the deals that it needs to maintain its continued growth.

Table 7
Sofamor Danek Group, Inc.
Quarterly Income Statement*

(Dollars in thousands)	1996					1997					1998E					1999E				
	1st	2nd	3rd	4th	Annual	1st	2nd	3rd	4th	Annual	1st (A)	2nd	3rd	4th	Annual	1st	2nd	3rd	4th	Annual
Revenues	54,218	56,820	63,206	70,281	244,525	69,759	73,613	78,006	91,524	312,902	88,453	**89,180**	**93,152**	**102,884**	**373,669**	**104,603**	**107,029**	**117,802**	**129,233**	**458,667**
COGS	10,616	9,731	10,363	14,295	45,005	12,370	12,660	14,631	18,407	58,068	15,748	**15,982**	**16,804**	**18,682**	**67,217**	**19,564**	**20,619**	**23,375**	**26,412**	**89,970**
Gross Margin	43,602	47,089	52,843	55,986	199,520	57,389	60,953	63,375	73,117	254,834	72,705	**73,198**	**76,348**	**84,201**	**306,452**	**85,038**	**86,411**	**94,427**	**102,821**	**368,697**
SG&A	25,988	26,784	30,617	33,340	116,729	32,698	34,633	35,321	42,762	145,414	41,039	**41,576**	**42,990**	**46,915**	**172,519**	**47,222**	**47,834**	**52,122**	**56,608**	**203,786**
R&D	3,638	3,919	4,267	4,102	15,926	4,730	4,767	4,822	5,428	19,747	6,234	**5,963**	**6,023**	**6,053**	**24,274**	**7,056**	**7,157**	**7,617**	**7,604**	**29,433**
Total Operating Expenses	29,626	30,703	34,884	37,442	132,655	37,428	39,400	40,143	48,190	165,161	47,273	**47,539**	**49,013**	**52,968**	**196,793**	**54,277**	**54,991**	**59,739**	**64,212**	**233,219**
Operating Income	13,976	16,386	17,959	18,544	66,865	19,961	21,553	23,232	24,927	89,673	25,432	**25,659**	**27,335**	**31,233**	**109,659**	**30,761**	**31,420**	**34,687**	**38,609**	**135,477**
Nonoperating Income	980	90	(339)	182	913	76	179	(23)	(227)	5	246	**737**	**799**	**860**	**2,642**	**1,069**	**1,212**	**1,244**	**1,410**	**4,934**
Interest Expense	(777)	(795)	(1,119)	(1,053)	(3,744)	(1,176)	(1,515)	(1,530)	(1,318)	(5,539)	(1,135)	**(664)**	**(529)**	**(529)**	**(2,857)**	**(529)**	**(529)**	**(529)**	**(529)**	**(2,116)**
Earnings Before Taxes	14,179	15,681	16,501	17,673	64,034	18,861	20,217	21,679	23,382	84,139	24,543	**25,732**	**27,605**	**31,564**	**109,444**	**31,301**	**32,103**	**35,402**	**39,490**	**138,295**
Income Taxes	3,582	4,612	5,030	5,569	18,793	5,470	5,863	6,613	7,127	25,073	7,354	**7,951**	**8,557**	**9,816**	**33,679**	**9,784**	**10,115**	**11,243**	**12,642**	**43,784**
Income Before Minority Interest	10,597	11,069	11,471	12,104	45,241	13,391	14,354	15,066	16,255	59,066	17,189	**17,781**	**19,047**	**21,748**	**75,765**	**21,517**	**21,988**	**24,159**	**26,848**	**94,511**
Minority Interest	(412)	(437)	(446)	(179)	(1,474)	(617)	(701)	(662)	(302)	(2,282)	(694)	**(768)**	**(724)**	**(301)**	**(2,486)**	**(860)**	**(921)**	**(915)**	**(378)**	**(3,074)**
Net Income	10,185	10,632	11,025	11,925	43,767	12,774	13,653	14,404	15,953	56,784	16,495	**17,014**	**18,323**	**21,447**	**73,279**	**20,657**	**21,067**	**23,243**	**26,470**	**91,437**
Year-to-year Growth					**27%**					**30%**					**29%**					**25%**
Weighted Average Shares Outstanding	26,091	25,994	26,144	26,205	26,046	26,695	27,352	27,138	27,463	26,783	27,933	**28,525**	**28,762**	**29,000**	**28,555**	**29,052**	**29,102**	**29,151**	**29,201**	**29,126**
EPS	0.39	0.41	0.42	0.46	1.68	0.48	0.50	0.53	0.58	2.12	0.59	**0.60**	**0.64**	**0.74**	**2.57**	**0.71**	**0.72**	**0.80**	**0.91**	**3.14**
Year-over-year Growth	24%	28%	25%	19%	24%	23%	22%	26%	28%	26%	23%	19%	20%	27%	21%	20%	21%	25%	23%	22%

100% Income Statement	1996					1997					1998E					1999E				
	1st	2nd	3rd	4th	Annual	1st	2nd	3rd	4th	Annual	1st (A)	2nd	3rd	4th	Annual	1st	2nd	3rd	4th	Annual
Revenues	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**
COGS	19.6%	17.1%	16.4%	20.3%	18.4%	17.7%	17.2%	18.8%	20.1%	18.6%	17.8%	**17.9%**	**18.0%**	**18.2%**	**18.0%**	**18.7%**	**19.3%**	**19.8%**	**20.4%**	**19.6%**
Gross Margin	80.4%	82.9%	83.6%	79.7%	81.6%	82.3%	82.8%	81.2%	79.9%	81.4%	82.2%	**82.1%**	**82.0%**	**81.8%**	**82.0%**	**81.3%**	**80.7%**	**80.2%**	**79.6%**	**80.4%**
SG&A	47.9%	47.1%	48.4%	47.4%	47.7%	46.9%	47.0%	45.3%	46.7%	46.5%	46.4%	**46.6%**	**46.2%**	**45.6%**	**46.2%**	**45.1%**	**44.7%**	**44.2%**	**43.8%**	**44.4%**
R&D	6.7%	6.9%	6.8%	5.8%	6.5%	6.8%	6.5%	6.2%	5.9%	6.3%	7.0%	**6.7%**	**6.5%**	**5.9%**	**6.5%**	**6.7%**	**6.7%**	**6.5%**	**5.9%**	**6.4%**
Total Operating Expenses	54.6%	54.0%	55.2%	53.3%	54.3%	53.7%	53.5%	51.5%	52.7%	52.8%	53.4%	**53.3%**	**52.6%**	**51.5%**	**52.7%**	**51.9%**	**51.4%**	**50.7%**	**49.7%**	**50.8%**
Operating Income	25.8%	28.8%	28.4%	26.4%	27.3%	28.6%	29.3%	29.8%	27.2%	28.7%	28.8%	**28.8%**	**29.3%**	**30.4%**	**29.3%**	**29.4%**	**29.4%**	**29.4%**	**29.9%**	**29.5%**
Nonoperating Income	1.8%	0.2%	-0.5%	0.3%	0.4%	0.1%	0.2%	0.0%	-0.2%	0.0%	0.3%	**0.8%**	**0.9%**	**0.8%**	**0.7%**	**1.0%**	**1.1%**	**1.1%**	**1.1%**	**1.1%**
Interest Expense	-1.4%	-1.4%	-1.8%	-1.5%	-1.5%	-1.7%	-2.1%	-2.0%	-1.4%	-1.8%	-1.3%	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**	**-2.0%**
Earnings Before Taxes	26.2%	27.6%	26.1%	25.1%	26.2%	27.0%	27.5%	27.8%	25.5%	26.9%	27.7%	**28.9%**	**29.6%**	**30.7%**	**29.3%**	**29.9%**	**30.0%**	**30.1%**	**30.6%**	**30.2%**
Income Taxes ***(percentage of EBT)***	25.3%	29.4%	30.5%	31.5%	29.3%	29.0%	29.0%	30.5%	30.5%	29.8%	30.0%	**30.9%**	**31.0%**	**31.1%**	**30.8%**	**31.3%**	**31.5%**	**31.8%**	**32.0%**	**31.7%**
Income Before Minority Interest	19.5%	19.5%	18.1%	17.2%	18.5%	19.2%	19.5%	19.3%	17.8%	18.9%	19.4%	**19.9%**	**20.4%**	**21.1%**	**20.3%**	**20.6%**	**20.5%**	**20.5%**	**20.8%**	**20.6%**
Minority Interest	-0.8%	-0.8%	-0.7%	-0.3%	-0.6%	-0.9%	-1.0%	-0.8%	-0.3%	-0.7%	-0.8%	**-0.9%**	**-0.8%**	**-0.3%**	**-0.7%**	**-0.8%**	**-0.9%**	**-0.8%**	**-0.3%**	**-0.7%**
Net Income	18.8%	18.7%	17.4%	17.0%	17.9%	18.3%	18.5%	18.5%	17.4%	18.1%	18.6%	**19.1%**	**19.7%**	**20.8%**	**19.6%**	**19.7%**	**19.7%**	**19.7%**	**20.5%**	**19.9%**

* Adjusted for one-time charges

Table 8
Sofamor Danek Group, Inc.
Cash Flow Statement

(Dollars in thousands)	1996 Annual	1997 Annual	1998E Annual	1999E Annual
Cash from Operating Activities:				
Net Income	11,267	56,784	**73,279**	**91,437**
Reconciliation of Net Income to Net Operating Cash				
Depreciation and Amortization	10,374	16,629	**11,274**	**11,605**
Doubtful Accounts Receivable	705	504	**525**	**578**
Deferred Income Tax Benefit	(18,678)	(1,710)	**(1,699)**	**(2,826)**
Loss on Disposal of Equipment	94	94	**0**	**0**
Equity Loss in Unconsolidated Affiliate	49	0	**0**	**0**
Minority Interest	1,474	2,282	**2,486**	**3,074**
Changes in Assets & Liabilities (Net Acquisitions)				
Accounts Receivable	(19,606)	(25,007)	**(22,196)**	**(35,904)**
Other Receivables	(6,968)	(12,794)	**(3,301)**	**(3,631)**
Inventories	(9,777)	(17,489)	**(20,893)**	**(25,301)**
Prepaid Expenses	(1,142)	77	**(162)**	**(755)**
Prepaid Income Taxes	2,647	(3,054)	**(4,062)**	**(2,048)**
Other Assets	(26,709)	(3,328)	**(351)**	**0**
Accounts Payable	(357)	(2,120)	**6,287**	**3,413**
Accrued Income Taxes	6,186	6,349	**1,306**	**1,088**
Accrued Expenses	13,353	6,206	**(3,314)**	**16,163**
Current Portion of Product Liability Litigation	0	0	**4,379**	**750**
Product Liability Litigation	48,000	(7,424)	**(13,947)**	**(8,682)**
Cash Provided by Operating Activities	10,912	15,999	**29,611**	**48,961**
Cash from Investing Activities				
Purchase of Short-term Investments	(116)	(347)	**(44)**	**0**
Proceeds From Maturities of Short-term Investments	1,899	405	**0**	**0**
Proceeds From Sale of Equipment	34	774	**0**	**0**
Purchase of PP&E	(7,110)	(10,293)	**(3,994)**	**(4,292)**
Purchase of Intangible Assets	(18,538)	(22,746)	**0**	**0**
Increase in Notes Receivable (Other)	0	(1,716)	**0**	**0**
Repayments of Notes Receivable (Other)	85	358	**0**	**0**
Acquisitions (net of acquired cash)	(33,953)	(1,420)	**0**	**0**
Investment in Unconsolidated Affiliates	0	(146)	**0**	**0**
Purchase of Minority Interest	(1,965)	(483)	**(2,486)**	**(3,074)**
Cash used by Investing Activities	(59,664)	(35,614)	**(6,524)**	**(7,366)**
Cash from Financing Activities				
Increase in Short-term Borrowing	43,839	36,243	**(11,073)**	**0**
Proceeds from Long-term Debt	871	19,678	**0**	**0**
Repayment of Long-term Debt	(10,353)	(52,438)	**(37,550)**	**0**
Repayment of Shareholders' Notes Receivable	450	450	**0**	**0**
Proceeds From Issuance of Common Stock	5,574	13,103	**276,532**	**0**
Repurchase of Common Stock			**(188,205)**	**0**
Capital Contribution from Minority Shareholders	489	148	**0**	**0**
Cash Provided (Used) by Financing Activities	40,870	17,184	**39,704**	**0**
Effect of Exchange Rates on Cash	(618)	2,330	**3,181**	**2,376**
Increase (Decrease) in Cash	(8,500)	(101)	**65,972**	**43,971**
Cash Beginning of Period	11,330	2,830	**2,729**	**68,701**
Cash End of Period	2,830	2,729	**68,701**	**112,672**

Table 9
Sofamor Danek Group, Inc.
Balance Sheet

(Dollars in thousands)	1996 Annual	1997 Annual	1998E Annual	1999E Annual
Assets				
Cash and Cash Equivalents	2,830	2,729	**68,701**	**112,672**
Short-term Investments	111	36	**100**	**100**
Accounts Receivable	70,031	88,209	**109,880**	**145,206**
Other Receivables	15,813	29,374	**32,675**	**36,306**
Inventories				
Finished Goods	28,260	35,029	**46,119**	**60,397**
Work-in-process	2,961	3,405	**5,607**	**7,343**
Raw Materials	2,262	2,141	**3,243**	**4,247**
Total Product Inventories	33,483	40,575	**54,969**	**71,987**
Loaner Set Inventories	14,123	21,511	**28,011**	**36,293**
Prepaid Expenses	6,318	6,061	**6,223**	**6,978**
Prepaid Income Taxes	0	3,052	**7,114**	**9,162**
Current Deferred Income Taxes	5,312	8,013	**9,816**	**12,642**
Total Current Assets	148,021	199,560	**317,488**	**431,346**
Property, Plant and Equipment				
Land	1,484	1,477	**1,480**	**1,480**
Buildings	11,261	10,905	**10,905**	**10,905**
Machinery and Equipment	32,083	35,677	**39,459**	**43,694**
Automobiles	708	759	**968**	**1,024**
Gross PP&E	45,536	48,818	**52,812**	**57,103**
Accumulated Depreciation	(20,026)	(23,797)	**(27,862)**	**(32,259)**
Net PP&E	25,510	25,021	**24,950**	**24,845**
Intangible Assets				
Goodwill	41,957	46,125	**46,125**	**46,125**
Patents	33,960	39,865	**39,865**	**39,865**
Trademarks	1,767	1,897	**1,897**	**1,897**
License Agreements	9,009	12,062	**12,062**	**12,062**
Non-compete Agreements	6,528	15,888	**15,888**	**15,888**
Other	3,770	1,378	**1,378**	**1,378**
Gross Intangibles	96,991	117,215	**117,215**	**117,215**
Accumulated Amortization	(13,565)	(20,167)	**(27,376)**	**(34,584)**
Net Intangibles	83,426	97,048	**89,839**	**82,631**
Investments	920	954	**934**	**934**
Other Assets	28,282	31,649	**32,000**	**32,000**
Non-current Deferred Income Taxes	33,002	31,425	**31,425**	**31,425**
Total Assets	319,161	385,657	**496,636**	**603,180**
Liabilities And Equity				
Notes Payable and Lines of Credit	50,207	11,731	**7,744**	**7,744**
Current Maturities of Long-term Debt	16,687	7,586	**500**	**500**
Current Portion of Product Liability Litigation	0	8,606	**12,985**	**13,735**
Accounts Payable	7,332	4,684	**10,971**	**14,383**
Income Taxes Payable	3,898	2,473	**3,779**	**4,867**
Accrued Expenses	38,770	41,488	**38,174**	**54,337**
Deferred Income Taxes	0	0	**0**	**0**
Total Current Liabilities	116,894	76,568	**74,153**	**95,567**
Long-term Debt, Less Current Maturities	12,300	60,650	**23,100**	**23,100**
Deferred Income Taxes	121	0	**104**	**104**
Product Liability Litigation	48,000	33,970	**20,023**	**11,341**
Minority Interest	2,020	3,171	**3,171**	**3,171**
Preferred Stock	0	0	**0**	**0**
Common Stock and Paid-in Capital	52,994	74,014	**350,546**	**350,546**
Retained Earnings	98,044	154,828	228,107	319,544
Accumulated Other Comprehensive Loss	2,542	(4,294)	**(1,113)**	**1,263**
Less:				
Cost of Common Stock Held in Treasury	(9,985)	(9,985)	(198,190)	(198,190)
Unearned Compensation	(54)	0	**0**	**0**
Stockholder's Notes Receivable	(3,715)	(3,265)	**(3,265)**	**(3,265)**
Total Common Equity	139,826	211,298	**376,085**	**469,898**
Total Liabilities and Equity	319,161	385,657	**496,636**	**603,180**

Valuation

On the basis of its expected earnings per share for 1998 and 1999, with resulting price-to-earnings multiples of 34.2 and 28.0, respectively, SDG is priced comparably both to major device companies with significant spinal product lines and other leading device companies (see table 10). Recently, the only other public pure spinal device company, Cross Medical, merged with Interpore. In addition, during its last independent year Cross Medical only had sales of $13 million. Consequently, one should compare SDG with the other major device firms having spinal product lines, as well as the greater medical device universe at large. When compared to these firms, SDG's expected price-to-earnings ratios rank near the top, just below Medtronic and Boston Scientific, and just ahead of Guidant, and Becton Dickinson as shown in figure 33. When comparing both long- and short-term growth rates with P/E multiples across the major device firms, there is a strong correlation that explains SDG's high multiple (refer to figure 34). This result appears even stronger in the smaller subset of firms with substantial spinal products lines (see figure 35).

Therefore, we believe that Sofamor Danek's valuation multiple is justified, and rate SDG shares a very attractive Long-term Buy. We believe that the company has earned, and should continue to earn, a premium on the basis of its financial and growth performance.

Additional information is available upon request.

DJIA:	9171.48
S&P 500:	1119.06
NASDAQ:	1831.75

The prices of the common stock of other public companies mentioned in this report follow:

American Home Products	$51 1/16
C.R. Bard	$33 11/16
Bausch & Lomb	$49 1/8
Baxter	$57 15/16
Becton Dickinson	$72 1/4
Biomet	$28 1/8
Boston Scientific	$68 3/4
Bristol-Myers Squibb	$112 15/16
Collagen	$19 7/8
Creative Biomolecules	$6 1/4
DePuy	$28 15/16
GE	$85 11/16
Guidant	$67 3/16
Interpore Cross	$6 3/8
Medtronic	$51 11/16
Orthofix	$13 5/16
Osteotech	$19 45/64
Pfizer	$112 13/16
St. Jude Medical	$37 1/8
Stryker	$39 3/4
Sulzer Medica	$25 7/8
United States Surgical	$35 5/8
Vista Medical Technologies	$7 15/16

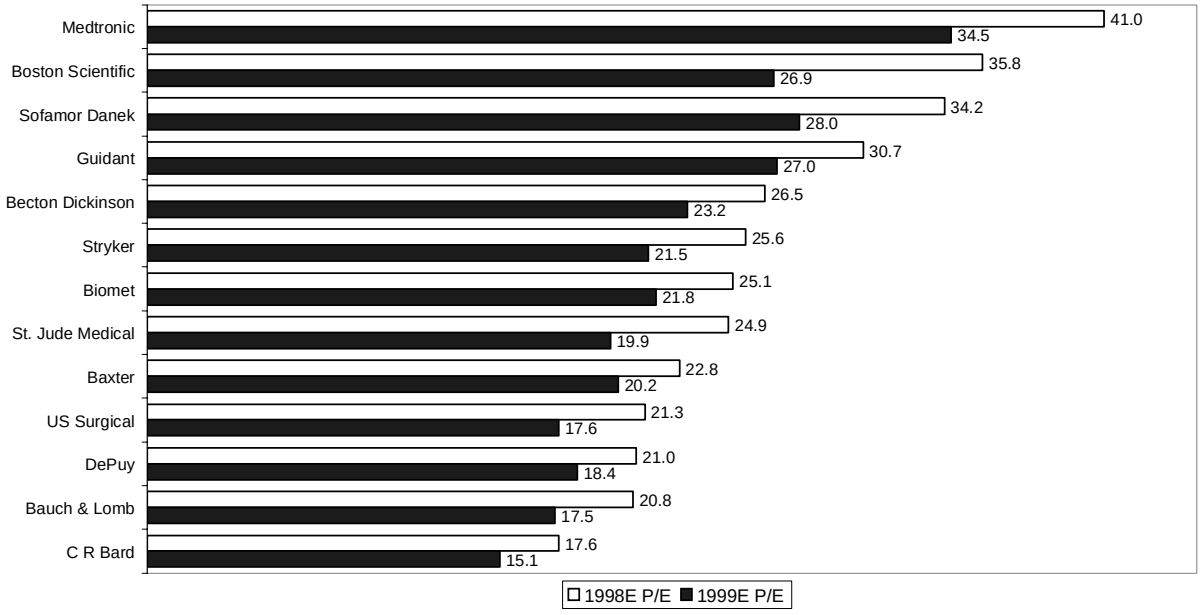
Table 10
Sofamor Danek Group, Inc.
Comparable Company Valuation Analysis*

		5/21/98 Price	1998E P/E	1999E P/E	Long-term EPS growth rates 1993-1998E	Long-term EPS growth rates 1993-1999E	Short-term EPS growth rate 1997-1999E
BOL	Bausch & Lomb	49 1/8	20.8	17.5	-6.0%	-2.2%	16.2%
BAX	Baxter	57 15/16	22.8	20.2			11.5%
BDX	Becton Dickinson	72 1/4	26.5	23.2	-0.6%	1.7%	13.8%
BMET	***Biomet***	***28 1/8***	***25.1***	***21.8***	***14.9%***	***14.9%***	***17.1%***
BSX	Boston Scientific	68 3/4	35.8	26.9	22.4%	24.1%	24.2%
BCR	C R Bard	33 11/16	17.6	15.1	3.6%	5.7%	11.6%
DPU	***DePuy***	***28 15/16***	***21.0***	***18.4***			***12.1%***
GDT	Guidant	67 3/16	30.7	27.0			37.3%
MDT	Medtronic	51 11/16	41.0	34.5	24.6%	23.6%	17.3%
SDG	Sofamor Danek	87 13/16	34.2	28.0	16.3%	17.2%	21.7%
STJ	St. Jude Medical	37 1/8	24.9	19.9	-0.9%	3.1%	32.8%
SYK	***Stryker***	***39 3/4***	***25.6***	***21.5***	***19.7%***	***19.7%***	***20.2%***
USS	***US Surgical***	***35 5/8***	***21.3***	***17.6***			***12.0%***

*SDG EPS; William Blair & Company, L.L.C. estimates; other, First Call estimates

Source: Various company financial statements; First Call; Fidelity; William Blair & Company, L.L.C. analysis

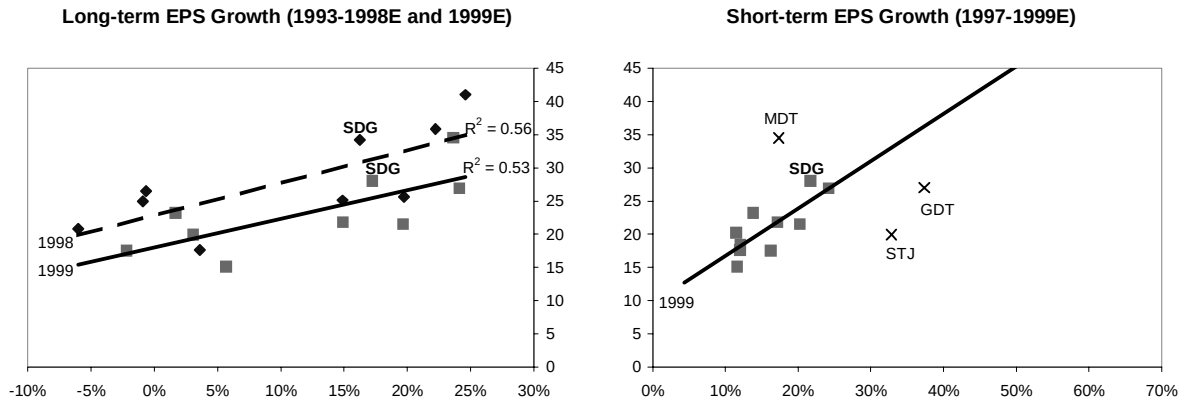
Figure 33
Sofamor Danek Group, Inc.
Comparable Major Medical Device P/Es



*SDG: William Blair & Company, L.L.C. estimates; others First Call estimates

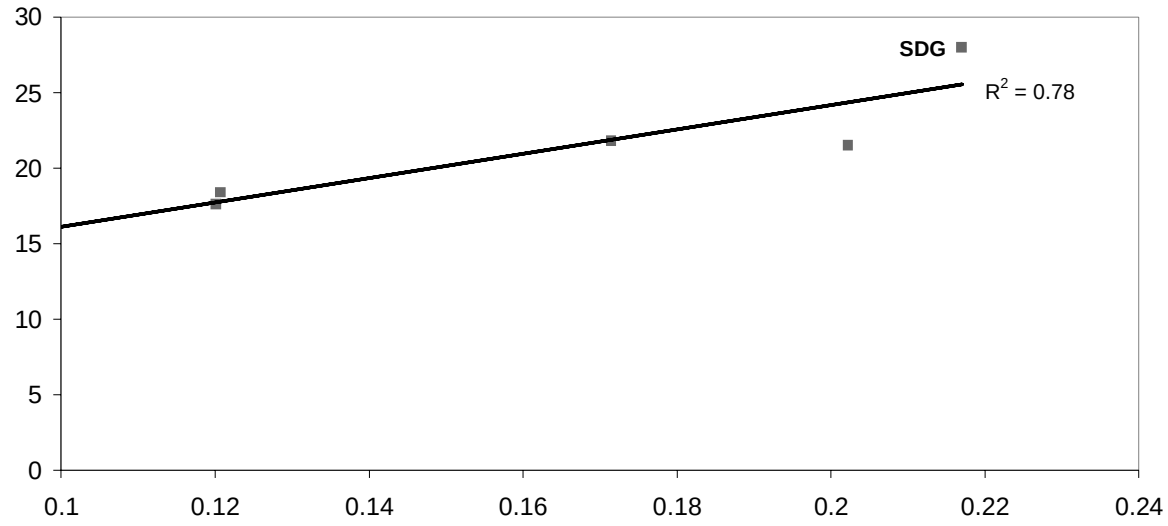
Source: Various company financial statements; First Call; Fidelity; William Blair & Company, L.L.C. analysis

Figure 34
Sofamor Danek Group, Inc.
Comparable Major Medical Device P/Es Versus Long- and Short-term CAGR



Source: Various company financial statements; First Call; Fidelity; William Blair & Company, L.L.C. analysis

Figure 35
Sofamor Danek Group, Inc.
Comparable Major Orthopedic Device with Spine Products
P/Es Versus Short-term CAGR



Source: Various company financial statements; First Call; Fidelity; William Blair & Company, L.L.C. analysis

Appendix A: Basics of the Anatomy of the Spine and Axial Skeleton

SDG is focused on the spine and related bones, forming the axial skeleton of the body. The axial skeleton comprises the vertebrae of the spine, the skull, the thoracic or rib cage and sternum. This is in contrast to the appendicular skeleton, which encompasses the bones of the upper and lower limbs.

The spine itself comprises 24 mobile vertebrae connected by intervertebral discs. These vertebrae are typically categorized by their location in the back, with the highest seven in the neck designated cervical (C1-C7); the next 12 mid-back vertebrae connected to the rib cage called thoracic (T1-T12), and the remaining five low-back, or lumbar, vertebrae (L1-L5). The cervical spine attaches to the cranium on top, and the lumbar spine attaches below to the sacrum, part of the pelvis. Extending to the back (dorsally) from the vertebrae are the pedicles, connected by bone bridges (the lamina) that help create the vertebral arch, thus forming the vertebral foramen, through which passes the spinal cord. Projecting from the arch are three bony protrusions (processes), the central one called the spinous process and the lateral protrusions labeled the transverse processes, which serve as attachments for muscles and ligaments.

Connecting the vertebrae are the discs, forming a "three-joint complex." Discs are cushions that help to absorb the load on the spine. Each disc is made of two parts, the outer annulus (fibrosis) and the inner nucleus (pulposus). The annulus, which connects the disc to each vertebrae, is made from predominantly type II collagen layered in an alternating fashion. The nucleus begins as 80% water when an individual is young, but dehydrates as one ages. Also, as force is applied to the nucleus, water is forced out, returning after the load is removed. Starting at about age 30, the water content of the nucleus begins to decline, shifting the load from the nucleus to the annulus, which in turn may cause a degenerative condition (see descriptions below).

The term cranium generally is used to refer to the skull minus the lower jaw, or mandible. The skull is the most complex skeletal anatomy of the body. It comprises the eight bones that surround the brain and the 14 bones that form the skeleton of the face.

Appendix B: Medical Conditions That Occur in the Spine and Axial Skeleton

Various medical conditions arise in the spine and cranium, for which medical devices are used as part of treatment (see table 11). These broadly fall into three categories: 1) the lower and mid-back (thoracolumbar region)—degenerative disc disease, deformity, and tumor/trauma; 2) the neck (cervical region)—degenerative disc disease and injury; and 3) the head (cranial or maxillofacial region)—trauma, reconstruction, and tumor. For each, different treatments exist—some based on devices and some not. After discussing the possible medical conditions, we describe device-oriented treatments, although we include other treatments as necessary to understand the market.

Table 11
Sofamor Danek Group, Inc.
Medical Conditions of the Spine and Treatments

Condition	Treatment	Devices / procedures
Lumbar and Thoracic		
Degenerative disc disease / low back pain	Preliminary conservative approach (no "red flags" signaling fracture, tumor, or infection) - Analgesics - Modified activity - Limited bed rest	
Dysfunction / herniated disc	***Decompression (discectomy/ laminectomy)***	- *Open discectomy* - *Endoscopic discectomy* - *Chemonucleolysis* - *Automated percutaneous nucleotomy* - *Laser nucleotomy*
Instability / spondylolisthesis	***Fusion***	- *Internal fixation* - *Interbody cages* - *Prosthetic disc*
Restabilization / spondylosis / spinal stenosis	- ***Decompression*** - ***Fusion***	*Same as both above*
Deformity		
Scoliosis	- *Watchful waiting* - *Bracing* - ***Permanent internal fixation*** - ***Fusion***	- *Braces* - *Hook and rod instruments*
Kyphosis	- *Watchful waiting* - *Treatment of underlying cause (e.g., osteoporosis)* - *Bracing* - ***Internal fixation / fusion***	- *Same as aboves*
Tumor / trauma		
Tumor	- ***Chemotherapy / radiation*** - ***Excision and filling*** - ***Internal fixation / fusion***	- *Bone growth enhancers* - *Fixation*
Trauma	- *External fixation* - Internal fixation / fusion - ***Mesh / plate reinforcement***	*Same as above*
Cervical / Neck		
Disc degeneration	**Comparable to lumbar degenerative disc disease**	- Internal fixation (specific to cervical region) - External fixation ("halo")
Injury	- Conservative approach when appropriate, including neck brace - External fixation - *Internal fixation / fusion* - **Mesh / plate reinforcement**	- Same as above, plus - Neck brace
Cranial		
Trauma	- **Mesh / plate reinforcement**	- Titanium mesh - Bone growth enhancers
Reconstruction	- **Mesh and plastic formed shapes**	- Titanium mesh - Bone growth enhancers
Tumor	- **Surgical excision / extraction or hard or soft tissue** - **Stereotactic radiosurgery** - Radiation or chemotherapy as secondary or adjuvant treatment	- Titanium mesh - Image-guided surgery - Bone growth enhancers

Source: AAOS; NASS; *Spine*; New England Journal of Medicine; NYU Department of Neurology; American Journal of Public Health; *Safety & Health Business & Health*; National Center for Health Statistics; U.S. Census Bureau; Agency for Health Care Policy and Research; MDI; Interviews; William Blair & Company, L.L.C. analysis

Thoracolumbar Disorders

Degenerative diseases of the spine. As one ages, there are degenerative changes to the disc and other spinal structures that can cause pain and reduced mobility or function. These changes may be divided into roughly three phases: dysfunction, instability, and restabilization.

Dysfunction. As the nucleus of the disc dehydrates, load on the annulus increases, often causing tears or fissures. Once this occurs, the nucleus can migrate to the point that it ruptures through the annulus or herniates. This herniated disc then can put pressure on a nerve root emanating from the spinal cord and cause pain or tingling. In addition, the nucleus, which was avascular and sheltered from the immune system, may become recognized and engender an inflammatory response.

Instability. Even without disc herniation, the dehydration of the disc can cause a loss of disc height, which may be combined with laxity of the ligaments to cause increased motion, leading potentially to degenerative spondylolisthesis—the displacement of one vertebra over another. The loss of disc height or this displacement also can lead to a reduction in the size of vertebral foramen, compressing the nerve roots. This results in a variety of syndromes associated with herniation, depending on the disc affected (see table 12).

Restabilization. Severe degeneration leads to hypertrophy (overgrowth) of the bone (e.g., lamina), ligaments, and even the intradisc collagen due to the body's attempt to restabilize the vertebral joint. This creates a condition called spondylosis, or stiffening of the vertebrae. There also may be a condition called spinal stenosis—the reduction in space for the nerve root, again causing pain or other nerve sensations.

Table 12
Sofamor Danek Group, Inc.
Lumbar Disc Herniation Syndromes

Disc Level	Relative Frequency	Root Affected	Weakness	Pain	Sensory Loss	Reflex
L3-L4	5%	L4	Quadriceps	Front of thigh	Middle of ankle	Knee jerk
L4-L5	40-45%	L5	Extension of big toe	Back of thigh	Big toe	None
L5-S1	45-50%	S1	Ankle	Back of thigh & side of calf	Side of foot & heel	Achilles

Source: NYU Department of Neurology; William Blair & Company, L.L.C.

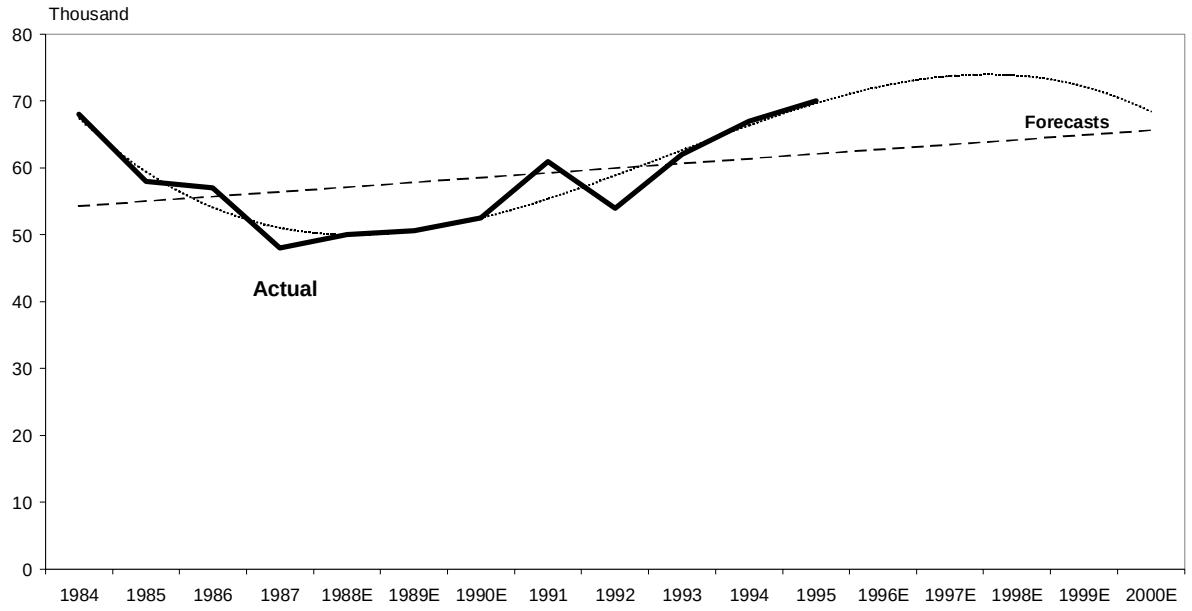
Deformities. The major deformities of the spine are scoliosis and kyphosis, both resulting from abnormal curvatures of the spine. These conditions result in the approximately 60,000 admissions to United States hospitals each year for curvature of the spine, a number that is slowly rising (see figure 36, on the facing page).

Scoliosis. A normal spine curves front to back. Scoliosis is the condition when the spine curves from side to side. For some individuals, vertebrae may even be twisted slightly creating the appearance of uneven shoulders. Other symptoms include prominent shoulder blades, elevated hips, leaning to one side, or an uneven waist. This condition affects about 2% of the population. However, if someone in a family has scoliosis, then the likelihood for others in the same family is approximately 20%. Scoliosis usually develops in children before puberty and affects more girls than boys. Most often its cause is unknown, or idiopathic. In severe cases, especially during adulthood, this condition can lead to severe back pain and difficulty breathing.

While scoliosis is not preventable, it can and should be treated during a child's growth years to prevent the complications that can arise later. Most improper curves remain small and only have to be watched, or the child may need to use a brace to keep the condition from getting worse. If the curve is severe or if a brace does not work, surgery is often necessary. According to the American Academy of Orthopaedic Surgeons (AAOS), exercise, manipulation, and electrical stimulation of the muscles have not been found effective.

Kyphosis. Round back is most often caused by osteoporosis. As one ages, osteoporosis may weaken the spongy (trabecular) bone of the vertebral body. Excessive loads that compress the spine, for example caused by lifting, bending forward, or even misstepping while walking, may squeeze the vertebral body into a wedge shape that causes the back to become "round." Because the posterior parts of the spine are still intact, these fractures may be reasonably stable, with only the kyphosis or loss of vertebral height as an indication of a problem. These fractures almost always heal, because the trabecular bone still has a good blood supply. In addition, there is rarely any compression of the nerve roots or spinal cord. However, there is still excessive stress on the musculoskeletal system that can lead to back pain and increase risk of osteoarthritis or spondylolisthesis. Kyphosis also may be a characteristic result of Parkinson's disease, due to the altered striatal nerve activity with the imbalance between right and left, as well as trauma or birth defects.

Figure 36
Sofamor Danek Group, Inc.
U.S. Hospital Admissions for Curvature of the Spine



Source: Various company financials; National Center for Health Statistics; U.S. Census Bureau; MDI; MarketLine; Theta; Frost & Sullivan; Dun & Bradstreet; Industry Interviews; William Blair & Company, L.L.C. analysis

Trauma/tumor. The spine, like other parts of the skeleton, is subject to traumas such as fractures, as well as bone neoplasms (tumors). The most typical cause for traumas is car accidents. While not all are trauma-related, there are more than 3 million visits to emergency rooms each year for back-related symptoms. Traumas to the back need attention because the back serves a load-bearing function without which one cannot walk, has difficulty getting around, and may not provide the proper cavity for internal organs. Removal of tumors also compromises the integrity of the spine and its weight-bearing function.

Cervical Disorders

Neck injury and pain can be caused by problems with both the spinal joints, as well as more commonly ailments of the soft tissue such as the muscles or ligaments. Regarding spinal causes, there can be cervical disc degeneration as with the low and mid-back, as well as a high number of traumatic neck injuries.

Cervical degeneration. Beginning at about age 40, the cervical disc begins to degenerate, and one can experience a herniated cervical disc and other degenerative changes similar to other back regions. However, unlike the lumbar back where only nerve roots are present, in the cervical region, the spinal cord may be compressed. When the spinal cord is compressed, there may be more generalized weaknesses caused by cervical myelopathy—for example, weakness in both hands and legs, or difficulty walking. If there is compression of the nerve roots, one experiences radiculopathy (see table 13). As degeneration progresses, it is also possible to experience narrowing of the spinal canal (cervical spondylosis), as with the mid- and lower back, with systems similar to those of a herniated cervical disc.

Cervical injury. Due to the neck's flexibility and attachment to the head, it is vulnerable to injury, often from sports, car accidents, and falls. There can be fractures or dislocations that can damage the spinal cord so severely that it can cause paralysis (quadriplegia). More common, however, is extreme movement forward or backward causing soft-tissue strain or damage.

Table 13
Sofamor Danek Group, Inc.
Cervical Disc Herniation Syndromes

Disc Level	Relative Frequency	Root Affected	Weakness	Sensory Loss	Reflex
C4-C5	2%	C5	Deltoid	Side of shoulder	Deltoid & pectoralis
C5-C6	20%	C6	Biceps	Side of arm & forearm, thumb & side of index finger	Biceps
C6-C7	68%	C7	Triceps & wrist extension	Middle finger	Triceps
C7-T1	10%	C8	Hand & wrist flexion	Ring & little finger	Finger flexion

Source: NYU Department of Neurology; William Blair & Company, L.L.C.

Cranial Disorders

Much of the cranial market is trauma-related, along with reconstructive and stereotactic surgery. There are an estimated 100,000 deaths each year from head injuries, with 700,000 people hospitalized and more than 50,000 people permanently disabled. These traumatic injuries most often are caused by acceleration and contact—for example a car or bike accident—and are the most frequent cause of disability and death due to nervous system disorders. Head injuries can be classified as primary or secondary. Primary injuries include cranial fractures, bruising or laceration of the brain, or hemorrhages inside the skull. Secondary injuries occur due to later hemorrhages or fluid buildup that causes a lack of blood and oxygen to the brain, as well as possible infections or seizures. Reconstructive surgery can result from trauma or congenital abnormalities, or be undertaken for cosmetic purposes.

Tumors of the central nervous system include both brain and the less-common spinal cord tumors. In the United States, primary brain tumors occur at a rate of about 11 per 100,000 people, leading to more than 28,500 primary tumors per year, with an additional 80,000 secondary or metastatic tumors derived from other forms of cancer. Brain tumors are the second most common cause of cancer death for children under the age of 15, as well as for those age 15-34. Surgery is the most common treatment for accessible brain tumors and serves four purposes: to extract as much of the tumor as possible (craniotomy); to provide access for other secondary or adjuvant treatments such as chemotherapy or radiation; to provide as definitive a diagnosis as possible (biopsy); and to insert shunts if necessary to remove excess fluid caused by some tumors, which increases intracranial pressure. Stereotactic surgery is often used, in which a three-dimensional image is created using imaging techniques such as an MRI and high doses of radiation are delivered to the precise location.

Appendix C: Medical Devices for Treating Spinal Disorders

Surgical Intervention for Degenerative Disc Disease

For degenerative conditions, a few criteria often need to be met before using surgery for correction. First, more-conservative measures, such as modified physical activity possibly combined with pain medication, should have failed. Second, there should be evidence of nerve compression, both through diagnostic imaging, as well as physical symptoms. Third, extreme mobility (hypermobility) should be such that normal movement could cause or has caused nerve damage.

Once these criteria for surgical intervention have been met, there are two accepted methods to relieve the symptoms—decompression and fusion. Decompression removes either the protruded portion of the disc (discectomy) or portions of the bone laminectomy, or both, to relieve the pressure on the nerves. Fusion causes two or more vertebrae to grow together in one bone mass to limit movement, thus regaining stability. In addition to these two proven methods, surgeons and device companies are experimenting with prosthetic discs to replace the entire "three-joint complex" of the vertebrae.

Internal Fixation and Fusion

Traditional Low- and Mid-back Fixation Devices

Since the early 1900s, both fusion and rudimentary instrumentation has been used to surgically correct spinal conditions. Beginning in the 1950s, hooks, rods, and wire—the Harrington System—became widely accepted and the "gold standard." The 1980s saw more-modern developments, which since have proliferated in the 1990s. Now there are screws and multiaxial screws for easier attachment during surgery, along with compact and low-profile instrumentation, especially useful for permanent implantation and deformities. These products typically cost between $1,500 and $3,000 per surgery depending on the number of levels fused, although the cost can exceed $5,000 for some long-back surgeries to correct deformities. The average total cost of the surgery is about $25,000 to $30,000.

Interbody (Fusion) Cages

In addition to the traditional hook, rods, plates, and screws, there are now devices that are placed within the spine to promote fusion and restore disc height that is lost in virtually all fusions, both (traditionally) instrumented and non-instrumented. Of course, these devices also need to retain or enhance stability until new bone has fused the vertebral segments, and they certainly should not lessen the potential for this new bone growth. Ideally, a device also would promote the proper front to back curve (lordosis) of the spine.

There are three types of interbody cages—horizontal threaded cylinders, open boxes and vertical rings—each with a biological bone graft equivalent. Horizontal cylinders are comparable to cortical bone dowels, open boxes to box-shaped cortical grafts, and vertical rings to femoral cortical rings. Lastly, in addition to the bone graft equivalents, cages are made of two materials, metal and carbon fiber; however, SDG has a novel material for this purpose (see "Additional Horizontal Cage Products," below). The major products, cylinders and boxes, typically cost $1,900 each, with the total cost per surgery of nearly $5,000, due to the use of two cages per level of the spine fused and the number of levels fused on average.

- *Horizontal cylinders.* These are hollow, cylindrical, and most often threaded devices that are packed with bone material and inserted (screwed) into the intervertebral space to restore disc height and promote fusion of the bone around and through the cages, thus immobilizing the movement of the two adjacent vertebrae. They typically are inserted from the front (anterior) using a laparoscopic approach, and they often are placed in pairs. The principal surrounding cylindrical cages was discovered while Dr. George Bagby, an orthopedic surgeon, was working with veterinary surgeons to treat

"wobbler syndrome" in horses. The resulting Bagby Basket was successful in achieving fusion of the spine in these treated horses. Dr. Bagby partnered with Dr. Stephen Kuslich, who had worked for more than 10 years in the diagnosis and treatment of lower-back pain, to develop a cylindrical basket, now termed cage, for human use.

These devices as a whole perform well. Dish height is restored, and the horizontal cylinder can be placed through a smaller window than rings for example, with a larger window associated with less stability. Currently, there are two FDA-approved products in the U.S. market, Sulzer Spine-Tech's BAK™ cage and Surgical Dynamics' Ray Threaded Fusion Cage.

- *Open boxes.* In 1991, Brantigan developed a carbon-fiber, open-box cage for posterior implantation, which is currently the most popular cage of these types and marketed by AcroMed. These types of devices currently often require additional pedicle screw or plate instrumentation to manage the instability created by the extensive posterior approach. However, there is a significant amount of space for bone graft material as the box is in fact open. Theoretically, this should lead to improved and stable fusion. There have been numerous, serious morbidities with the use of these device; however, these complications have not been directly attributed to the device, but to the extensive posterior approach and pedicle screw/plate instrumentation. Consequently, newer designs of open-box cages have been developed for an anterior approach requiring less or no additional instrumentation.

- *Vertical rings.* Metallic vertical-ring devices have been used since at least the early 1970s. Disc height is restored sufficiently as long as there is not too much destruction of the facing ends of the vertebrae. Small teeth or ridges usually hold the ring in place and provide the stability. A distinct advantage of vertical rings is their ability to provide and excellent environment for fusion. However, there is a tradeoff between the volume available for bone graft and an increase in height to provide the proper spacing and lordosis. In addition, the greater window that is required of insertion, the greater the complications.

Prosthetic Discs

There are two main approaches to providing a prosthetic disc: replace the entire disc or only the water-filled nucleus. Not including the spacers, there are more than 30 synthetic disc designs discussed, patented, or in actual development. A good example of the first approach is the prosthesis developed by the Charite Hospital in 1982. It comprises two end-plates made of a cobalt-chromium alloy surrounding a lens-shaped disc made of high-molecular-weight polyethylene. This device has been implanted in patients since 1984. While results of recent designs have approached that of fusions, the performance of the prosthetic disc is limited by that of the polymer core, which continues to deform and wear. Dr. Charles Ray, inventor of the Ray threaded fusion cage marketed by Surgical Dynamics, has pursued the second approach by developing the RayMedica PDN™, a pillow-shaped implant made of a dehydrated hydrogel pellet encased in a polymer, polyethylene. This device, which usually is implanted in pairs, began clinical trials in the United States in December 1997 and received European regulatory approval (the CE mark) in March 1998. It important to note that for this approach to be possible, the annulus (stiff outer portion of the disc) must be intact to contain the artificial nucleus and to provide the attachment to the vertebrae.

Cervical Systems

For cervical use, there are internal fixation devices, predominantly anterior plate screw systems and still cervical wire, as opposed to the hook, rod, and screw systems for the thoracolumbar spine. There are also external, nonfixed neck braces, and external fixation

devices—"halo" systems. Currently, SDG supplies only internal fixation devices. Lastly, surgeons historically also have "whittled" a patient's own bone to make cervical disc spacers, sometimes requiring an additional 30-45 minutes of surgical time in the operating room.

Image-guided Surgery

Image-guided surgery (IGS) systems interactively display images generated by various imaging technologies such as MRI or CT scans. This allows surgeons to preplan their surgeries, as well as place their surgical instruments precisely during an operation, using software and technology that allows for the freehand use of surgical instruments. Prior to the advent of these systems, surgeons, especially neurosurgeons, had to use rigid frames attached to the body, most often the cranium, to localize areas on which to operate or target radiation for stereotactic radiosurgery.

Bone Growth Enhancers

To achieve the fusion required to mitigate the various spinal conditions, surgeons employ the patients own bone (autogenous bone graft) harvested both at the surgical site, but also supplement usually with bone from the top of the hip (iliac crest). Using autogenous bone graft is considered the gold standard for fusion. To achieve better results and higher fusion rates, surgeons also often incorporate the use of the instruments and implants described earlier for internal fixation and spacing. However, there are still significant issues with using only these two associated approaches.

The issues with the use of autogenous bone fall into four categories: failure to achieve adequate bone growth, donor site morbidity, not enough donor material, and metabolic hindrances for individual patients. First, the gold standard fails up to 35% of the time, not achieving the necessary bone growth or fusion, even with instrumentation. Second, one must harvest the patient's own bone from the iliac crest. This requires a second surgery and the associated cost and time. Also, in maybe 25%-30% of the cases, there is pain or other morbidity at the donor site. Some patients who had fusion surgery complain that the donor site pain is worse than the original back pain. Third, there may not be enough donor material, either due to previous graft harvests, too much needed (for example, in the case of a multilevel fusion), or simply that the patient's own bone quality is insufficient. Fourth, individual patients may have other conditions that can slow down or prevent fusion. These include smoking, osteoporosis, or diabetes.

To address these shortcomings, bone growth enhancers have been developed. These enhancers are divided into 5 groups: processed bone from cadavers or animals (allografts or xenografts), synthetic grafts, bone growth factors, electrical stimulation, or ultrasound.

Bone graft materials. Various bone graft materials have a combination of three different properties that allow them to enhance new bone growth or fusion. The material can be osteogenic, osteoinductive, or osteoconductive. Osteogenic means that the material contains cells that can form bone and differentiate into bone-forming cells. For example, healthy autografts obviously contain viable bone or bone-precursor cells, as does bone marrow, which can be added to grafting materials. Osteoinductive means that the material will induce differentiation or growth. This induction may be biological or chemical, but it also could be mechanical or physical. Osteoconductive refers to a material that provides a scaffold or matrix that allows and supports ingrowth of bone cells, blood vessels, and bone. Table 14, on page 50, summarizes the bone growth properties of various materials.

Autografts have the greatest share of materials, accounting for more than 50% of the procedures, as shown in figure 17, on page 18. This percentage illustrates two points: The other products have gained a significant level of acceptance, and there is still significant room to grow. The cost for bone graft material other than autograft to the hospital is about $800 per procedure, or between $500 and $600 for the supplier, after subtracting the commission paid to the independent reps. The current potential value worldwide for bone grafts is estimated to be more than $600 million, with about one-half of this in the United States and about one-quarter in Japan.

In addition to their use in the spine, bone graft materials also are used for other orthopedic applications such as total joint replacement and skull or maxillofacial procedures. However, use in the spine is still greatest, with 46% of the total number of procedures in the United States (see figure 27, on page 30).

Allografts and xenografts. Allograft bone material is derived from processed human donor tissue, while xenografts are from animals. For allografts and xenografts, screening of donors and rigorous testing donor tissue is critical to ensure that infectious diseases are not transferred. Allograft bone can be preserved by either freezing or freeze-drying, and this should occur as soon after harvest as possible. Bone for freezing is brought to -70° to -196°C, and it can be stored for up to five years without a reduction in mechanical properties. Freeze-drying is more effective at reducing both the possibility for infection and an immune response from the recipient. The bone is dehydrated under a vacuum and can be preserved in this vacuum indefinitely. Processed bone also is sterilized either with gamma radiation or ethylene oxide, which appears to reduce the osteoinductivity and mechanical properties. Overall, however, many studies have shown good results with allografts. By decalcifying (demineralizing) allografts, a dimineralized bone matrix (DBM) is formed, which causes a lower immune response. In addition, it appears that some of the bone growth factors that exist in the extracellular matrix are preserved and made accessible, thus enhancing osteoinduction. Despite processing techniques, xenografts still often induce an immune response, even if only a mild one, and so therefore, their use is declining in favor of human tissue and synthetics.

An important characteristic of allograft tissue is that it is remodeled or incorporated into new bone. This is a cell-mediated activity, with the cells that normally eliminate bone, osteoclasts, and the cells that form new bone, osteoblasts, actively performing this process. Also, certain forms of allografts, specifically, specially made demineralized bone matrix, also have better handling characteristics than even natural bone because they come in putty or gel forms that are better for use during surgery

Synthetic grafts. There are a variety of synthetic bone graft materials, with various properties, including hydroxyapatite, bioglass, collagen, and calcium sulfate. Hydroxyapatite, such as that supplied by Interpore, is either granular or in block form, is only osteoconductive, and resorbs slowly if at all. Interpore is working with Quantic Medical to add superconcentrated platelets, ideally from the individual patient, to its material during surgery to impart osteoinductive properties. In addition, Interpore has introduced a more resorbable material in Europe. Bioglass currently is used only in periodontal surgery. However, some of its properties make it a potentially better synthetic. It is both osteoinductive and conductive without an additive, as well as resorbing more quickly, potentially in a cell-mediated way. Collagen and calcium sulfate both provide some osteoconductivity alone, but with better resorption than hydroxyapatite.

Table 14
Sofamor Danek Group, Inc.
Bone Growth Properties of Bone Graft Materials

	Type of Material	Osteoconductive	Osteoinductive	Osteogenic
Autograft	Natural	√	√	√
Allograft / xenograft	Natural	√	√	
Demineralized Bone Matrix (DBM)	Natural	√	√	
Bioglass	Synthetic	√	√	
Hydroxyapatite	Synthetic	√		
Collagen	Synthetic	√		
Calcium sulfate	Synthetic	√		

Source: *Spine*; MDI; Interviews; William Blair & Company, L.L.C. analysis

Competitors. The major competitors to autografts are the tissue banks that process allografts, either within an institution or regional not-for-profits. For commercial suppliers, the biggest is Osteotech—a supplier of allograft material—with more than 60% of the commercial market, followed by Interpore—a maker of the synthetic material hydroxyapatite—with more than 20% share (see figure 18, on page 19).

Bone growth factors. There are a variety of bone growth factors and sources. These growth factors stimulate or induce bone growth, thus have potential in both trauma and fusion spinal applications. The major growth factors pursued are bone morphogenetic proteins (BMPs) that are part of the human transforming growth factor b (TGF-b) superfamily of proteins, but there are also proteins from other families, nonhuman-derived proteins, and smaller peptides. In addition, a few companies are pursuing extracting, concentrating, or cloning specific osteogenic or osteoinductive cells.

- *Human TGF-b BMPs.* Currently, the most important growth factors of interest are BMPs derived from humans. In both animal and human clinical trials, these have been shown to increase both the rate and quality of bone growth and fusion. Six of the seven human BMPs discovered are related to each other in the TGF-b superfamily. These can be grouped into three sets, with one molecule in each set pursued commercially (see table 15, on the facing page). SDG is pursuing rhBMP-2 though its collaboration with the Genetics Institute (see below). Interpore is seeking to commercialize BMP-3 (Osteogenin) and Stryker Biotech (SYK) is proceeding with BMP-7 (OP-1) through its collaboration with Creative Biomolecules (CBMI). Only 0.1 % of bone proteins by weight are BMPs, and BMPs have effects on cells other than bone and cartilage. Therefore, there are some regulatory concerns regarding the concentration used, as well as the carrier or mechanism for placing and keeping the BMPs in the same site within the body. Companies are investigating various bone graft materials, as well as other materials (e.g., Hedrocel™ cage) as carriers.

- *Other growth factors.* In addition to human BMPs, companies are pursuing other growth factors. For example, Sulzer Orthopedics Biologics is developing a mixture of bovine-derived BMPs, Ne-Osteo. Sulzer is testing the product both alone and in conjunction with the BAK fusion cage of Sulzer Spine-Tech. It believes that a mixture will be better than a single factor and that a product extracted from cows will be much less expensive than a recombinant human protein. Obviously, there are both regulatory, as well as perceptual, issues regarding animal extracted versus recombinant proteins. One other growth factor being pursued is not a protein, but a water-soluble peptide one-tenth the

size, bone cell stimulating factor, BCSF™, from Allelix Pharmaceuticals and Millennium Biologix. There is some clinical evidence to date, but more scientific work needs to be done on this molecule.

Table 15
Sofamor Danek Group, Inc.
Comparison of BMPs

	Other Name	Firms Pursuing	Natural Tissue Sites	Chromo-some	Pre-protein Size	Size of Active Factor
BMP-2	**rh-BMP-2**	**SDG / GI**	**Bone, spleen, brain, lung, kidney, heart, placenta**	**20**	**396**	**114**
BMP-4			Bone, lung, kidney, brain, spleen, liver, heart, placenta	14	408	116
BMP-3	**Osteogenin**	**Interpore**	**Lung, brain**	**4**	**472**	**?**
BMP-5			Placenta	6	454	138
BMP-6			Skullcap, lung, brain, placenta, kidney, uterus, muscle, skin	6	513	139+
BMP-7	**OP-1**	**Stryker Biotech / CBMI**	**Kidney, placenta, brain, skullcap, spleen, lung, heart, liver, adrenal, bladder**	**20**	**431**	**139**

Source: Company financials; interviews; *Cellular and Molecular Biology of Bone*; *Spine*; William Blair & Company, L.L.C. analysis

- *Cells.* In addition to growth factors, one can envision using stem cells directly, or cells that produce osteoinductive factors. One of the most direct ways is to harvest a patient's own (autologous) bone marrow, but this is an additional painful procedure. Quantic Medical, working with Interpore, is taking an analogous, but less-painful approach, by developing a system to superconcentrate platelets during surgery from the patient's own blood. Quantic has shown an increased rate of bone formation using this approach. Osiris Therapeutics uses the patient's own bone marrow, but separates the mesenchymal stem cells (cells intended to differentiate into bone formation and resorption cells), then significantly expanding the number of cells in culture. This has the advantages of both reduced invasiveness and pain for bone marrow collection, as well as some data showing improved results versus fresh bone marrow or autografts.

Electrical stimulation. Human and animal clinical studies have shown that electrical stimulation reduces the time and increases the eventual success rate or spinal fusion. The appropriate currents seem to be between 5 and 25 microamps, which can be delivered through pulsed electromagnetic fields or applied directly. The increase in successful fusions has been reported to be 20%-30%. Use of electrical stimulation can add about $5,000 to the cost of a case. Examples of commercial electrical stimulation products are the SpF® internal spinal fusion stimulator from EBI (Biomet) and the Spinal-Stim® external stimulator from Orthofix.

Ultrasound. One last possible approach to biological enhancement is low-intensity pulsed ultrasound. This approach has been shown to accelerate fracture healing, for example to heal nonunion fractures. However, while this might be valuable in spine fusion, there is limited data available.

Discectomy

There are a wide variety of procedures to remove a herniated disc (discectomy). These procedures include open discectomy, chemonucleolysis, automated percutaneous nucleotomy, laser nucleotomy, minimally endoscopic approach from the back and side (posterolateral), or a midline endoscopic approach. Some of these approaches require or can take advantage of a procedure to remove also some of the bone that surrounds the spinal

cord, the lamina (laminectomy). The open discectomy is self-explanatory and most often performed with a microscope (microdiscectomy). Chemonucleolysis is the injection of an enzyme derived from the papaya root, chymopapain, into the nucleus of the disc to dehydrate it, reducing its volume and the pressure it is exerting on the nerves. There are disadvantages to this approach, including a potential allergic response; potential nerve damage if it contacts a nerve; the inability to reduce or remove the annulus of the disc or any bone that may be compressing a nerve; and the elimination of any remaining fluid in the disc, making the patient more susceptible to osteoarthritis. Automated percutaneous nucleotomy is the insertion of a hollow needle into the disc space through which a rotating cutter and vacuum are placed to remove the disc. Major disadvantages include the inability to remove any free-floating material or bone; clogging of the tip; difficulty in operating on the disc between L-5 and S-1, which accounts for almost 50% of lumbar disc herniations (see table 12). Laser nucleotomy is simply the application of a laser to usually an endoscopic procedure to vaporize (ablate) the nucleus. Again, it suffers the disadvantages of not having the ability to remove annular or bone tissue. Endoscopic discectomy approaches can be either from the back and side (posteriolateral) or straight in (midline). These are procedures that require a small, less-invasive opening than an open approach. While both have considerable advantages over other approaches, essentially obviating most of the disadvantages mentioned for the systems above, the midline approach is less complicated surgically and preferred by surgeons.

Cranial Surgery

Titanium mesh plates are used on the cranium to contain or fixate bone. They also are used in the jaw and facial bone for the same purpose, as well as to build shapes. The stereotactic surgery is predominantly the domain of image-guided surgery, as well as framed stereotactic systems. However, procedures often require a medical drill to open the cranium and titanium mesh to hold bone in place after surgery. In addition, drills are often needed to begin tapping the screw holes for trauma and reconstructive plates.

Appendix D
Sofamor Danek Group, Inc.
Major-competitor Product Matrix

Company	Lumbar/Thoracic Instruments	Cervical Systems	Interbody Fusion Cages*	Cranial	Bone Graft Substitutes	Bone Growth Factors	Image Guidance Systems	Discectomy Systems	Synthetic Discs
Sofamor Danek (SDG)	• TSRH® • CD Products • Colorado	• Orion™ • ACPii	• Novus® LC • MD-I and MD-II • MAN Carbon-fiber • Hedrocel	• TiMesh® • MedNext	• MD-I and MD-II	• rhBMP-2	• Stealthstation®	• MED System • Danekscope • TrimLine™	• Articulated Procelain Disc
DePuy Motech / *AcroMed* (DPU)	• Moss® Miami • VSP® • Isola® • Kaneda SR™ • University™ CASF™	• Peak™ • AcroPlate® • AcroMed Anterior Cervical • Bremer Halo • Songer Cable	• Surgical Titanium Mesh™ • Brantigan		• DynaGraft™ • VertiGraft™		• Viewpoint™	• Spine Tools™	• AcroFlex
Aesculap	• Mini ALIF • Socon	• Caspar	• Prospace PLIF • IVIS	• HiLAN Motor System • Acculan				• Spine Classics	• Prodisc
Interpore / *Cross Medical* (BONZ)	• Synergy™	• Synergy™	• Spinal Cage Implant		• Pro Osteon	• Osteogenin • Super-concentrated Platelets (Quantic)			
Osteonics / Dimso / Stryker Biotech (SYK)	• Osteonics® • Silkon™ • Diapason	• Halifax® Plus	• Ogival	• TPS Micro Bone Drills		• Novos™ (OP-1™)			
Synthes	• Universal • Anterior Spinal Plate • Titanium Locking Plate • Anterior Thoracolumbar • AO Schanz	• Anterior Cervical Plate • AO Cervical • Orozco	• AO Titanium Spacer • SynCage	• Titanium Mesh					
Surgical Dynamics (USS) / *Smith & Nephew (spine)*	• Rogozinski • Ultium • Simmons	• Aline™ • Anterior Cervical Plate (S&N)	• RAY® TFC					• Nucleotome Flex II • EndoFlex • AMD (S&N)	
Howmedica / Leibinger (PFE)	• BWM Spine System			• Leibinger®-Luhr®	• BoneSource®				• Hydrogel
Wright Medical	• Wrightlock® • Versalok®	• Michelson			• OsteoSet® • Collagen-based Prostheses • Resorbable Polymer				
Codman (JNJ)		• Codman®						• Karlin™	
Osteotech (OSTE)	• Zielke® VDS • SSCS		• Threaded Cortical Bone Dowels		• Grafton®				
SM *Spine-Tech* / SM Biologics (SM)			• BAK®			• Ne-Osteo™			
Elekta							• Leksell		
Midas Rex				• Midas Rex					
Radionics							• Optical Tracking System™		
RayMedica									• RayMedica PDN™
Zeiss							• STN		
Zimmer (BMY)	• Modulock				• Collagraft®				

Source: Company information

Appendix E: U.S. Regulatory Processes

Medical devices such as spinal implants and surgical systems are subject to government regulations in most countries. Therefore, SDG's success in part hinges on its ability to achieve the necessary approvals, and the time and expense of attaining those approvals.

FDA

The United States Food and Drug Administration regulates medical devices, as well as medicines, cosmetics, food, the feed and drugs for farm animals and pets, and even radiation-emitting products such as microwave ovens. To put this in perspective, the FDA regulates more than $1 trillion of products, or about one-quarter of each dollar spent each year by consumers in the United States

Federal Food, Drug, and Cosmetics Act

The FDA first was granted limited authority over medical devices in 1938 through the Federal Food, Drug, and Cosmetics Act. The original intent was to grant the FDA the authority to seize misbranded or adulterated devices that were part of interstate trade. However, the FDA expanded its stated authority in certain circumstances by declaring a device a drug, thus requiring premarket approval. This self-expanded authority was upheld by the Supreme Court.

Medical Device Amendments

In 1976, Congress enacted the Medical Device Amendments, specifically subjecting medical devices to federal regulation. The amendments required good manufacturing practices (GMP) and created three levels of devices based on risk—Class I through III. In addition, two types of potential premarket authorization were defined, the premarket notification, or 510(k), and premarket approval (PMA).

Three Classes of Medical Devices

Products are classified based on risk, with riskier devices subject to greater controls. Of the approximately 1,700 classified medical devices, 45% are Class I; 47%, Class II; and 8%, Class III.

Class I devices pose minimal potential for harm and are subject to general controls.

1) Register establishments with the FDA (strictly applies on U.S. establishments, but foreign establishments are encouraged also)

2) List devices to be marketed with the FDA

3) Use GMP to make the devices (some Class I devices are exempt from parts of GMP).

4) Label devices according to the proper labeling regulation

5) Submit 510(k) (premarket notification) prior to marketing a device (almost 75% of Class I devices are exempt from this)

Examination gloves and elastic bandages are examples of Class I devices

Class II devices are those for which special controls are needed, in addition to the general controls described above. These controls might be postmarket surveillance or special labeling requirements. Until 1998, these devices were never exempt from premarket

notification or GMP. Under the FDA Modernization Act of 1997, some Class II devices will be allowed an exemption from the 510(k) process. Infusion pumps and powered wheelchairs are examples of Class II devices.

Class III devices are controlled most strictly, because they sustain life, present a potentially unreasonable risk of injury, or are crucial to prevent impairment of health. A PMA is required before the device can be marketed. This is a scientific review process requiring clinical trials to prove the safety and effectiveness of the product. Replacement heart valves and silicone gel-filled breast implants are examples of Class III devices that used the PMA process.

Some Class III devices may not require a PMA and might be able to obtain 510(k) clearance. These are devices that can show substantial equivalence to a device marketed before May 28, 1976, and for which there has been no published regulation specifically requiring a PMA for that device. Endosseous implants and pulse generators for pacemakers are examples of Class III devices that currently require only a 510(k).

Table 16
Sofamor Danek Group, Inc.
Examples of Spinal Device Classifications

Product Type	Class	Product Code	Example	Process Required
AC-powered Motorized Surgical Instrument	1	GEY	MedNext™ 1000 drill	510(k)
Burrs and accessories for simple powered drills	2	HBE	MedNext™ bur	510(k)
Spinal Interlaminal Fixation Appliance	2	KWP	CD™ spinal system	510(k)
Spinal Intervertebral Body Fixation Appliance	2	KWQ	ACPii anterior cervical plate system	510(k)
Bone Fixation Plate	2	HRS	TiMesh® system	510(k)
Intervertebral Fusion Orthosis	3	MAX	Novus® LC*	PMA

* Not yet approved

510(k)

To utilize the 510(k) process, a new device must be shown to be substantially equivalent to a predicate device marketed prior to 1976. This means it has the same intended use and technological characteristics. Most devices, more than 90%, use the 510(k) process. The original act allowed a company to start marketing 90 days after submission if it had not received notification. However, this was amended through the SMDA to require the company to wait to receive a notice of substantial equivalence from the FDA.

PMA

A PMA requires a thorough review of human clinical trials, as well as other tests of the device. To begin the clinical trials for the PMA, a company must receive an investigational device exemption (IDE) after describing for the FDA the trial risks and protocols. However, prior to any human trials, a company must get approval from the institutional review board (IRB) of the institution where it will conduct the trial. The IRB is an expert panel that assesses the risks involved in the trial. If the IRB determines that the device represents an insignificant risk, this approval alone is sufficient to begin the trial. The trial results are then reviewed by the FDA regarding both safety and efficacy. After a PMA is granted, supplements must be submitted if there are any design, labeling, or manufacturing changes that might affect the safety or efficacy of the device.

Allograft Bone and Demineralized Bone Matrix (DBM)

Currently, banked human tissues are regulated through an interim rule—Human Tissue Intended for Transplantation—and therefore are not subject to the previsions of the Federal Food, Drug, and Cosmetic Act, such as premarketing clearance. This applies to the MD-I and MD-II cortical bone dowels.

Safe Medical Devices Act (SMDA) of 1990

This act strengthened the enforcement authority of the FDA to monitor products that are marketed. For example, the SMDA gave the FDA authority to impose substantial civil monetary penalties for particular violations. In addition, it required summary of safety and effectiveness data for 510(k) filings, postmarket surveillance for certain devices, and reporting of death or injuries attributed to a device.

Medical Devices Amendments of 1992

These amendments helped clear up (and clean up) some of the regulations under the SMDA. For example, it created a single definition for which injuries must be reported. Also, it gave the FDA more leeway in issuing repair, replace, or refund orders for devices presenting unreasonable risks. Lastly, it gave the FDA more time to finalize device-tracking regulations.

Food and Drug Modernization Act of 1997

At the end of 1997, the U.S. Congress enacted legislation that was intended to make the FDA review process less arbitrary and more competitive with world standards, without compromising the safety and efficacy of products marketed. The sections of the new law that apply to medical devices are highlighted below.

Investigational device exemptions (Section 201). When an applicant intends to perform a human clinical trial of any implantable or all Class III devices, the applicant has the opportunity to submit the plan in writing, and the FDA must meet with the applicant within 30 days. An official, binding record will be made of any agreement that is reached with the FDA.

Recognizing international device standards (Section 204). The FDA officially may recognize all or part of an international (or national) standard. Subsequently, an applicant may reference the standard in a Declaration of Conformity, which can be used to satisfy the requirement for a 510(k) or PMA. The FDA still may reject the declaration if the information supplied does not prove compliance with the standard or the standard does not apply.

Data requirements for devices (Section 205). Changes to the law affect 510(k)s, PMAs, and manufacturing under PMAs.

Labeling claims for 510(k)s. If the Office of Device Evaluation (ODE) determines the reasonable likelihood that a device will be used in an unintended way, which could cause harm, the ODE can require that a specific statement be placed in the labeling specifying the limitations for using the device. The device still would be found substantially equivalent.

Collaborative determination of PMA data requirements. An applicant can request a meeting with the FDA to determine in advance what data will be necessary to support the safety and effectiveness of its device. The FDA must meet with the applicant and provide within 30 days of the meeting a binding, written document that specifies what data is required to provide reasonable assurance. This method chosen also must be the least burdensome that will satisfy the needs.

Manufacturing under a PMA. Changes to the manufacturing process that could affect the safety or efficacy of a product require only a written notice to the FDA, not a PMA supplement.

Exemptions from 510(k), including specific Class II devices (Section 206). If a Class I device is not intended for use that presents an unreasonable risk or injury or is not of substantial importance in preventing impairment of health, then it will not require a 510(k). In addition, the FDA will specify certain Class II devices that do not require 510(k)s. Examples of Class II devices that it has specified to date are clinical mercury thermometers, wheeled stretchers, blood storage refrigerators, hematocrit measuring devices, and AC-powered adjustable hospital beds.

Risk-based classification of post-amendment Class III devices (Section 207). If an applicant receives a Not Substantially Equivalent (NSE) determination—placing the device into a Class III category—the applicant can request, within 30 days in writing, a reclassification of the product into Class I or II. The FDA has 60 days from the date of this request to classify the product in writing. If the device is classified Class I or II, then the applicant has received clearance and the device may be used by other applicants as a predicate device for 510(k)s.

Review time frames (Section 209). Changes were made to the law to further expedite the review processes for both 510(k)s and PMAs. Now, the law clearly states that the FDA must make 510(k) determinations no later than 90 days after receiving a submission. The FDA must meet with PMA applicants within 100 days of submission and prior to this meeting inform the applicant in writing of any deficiencies and what data would be needed to correct them.

Device tracking and postmarket surveillance (Sections 211 and 212). Manufacturers no longer automatically will be required to track devices or conduct postmarket surveillance. However, the FDA specifically can require that certain Class II or III devices be tracked or that postmarket surveillance be performed if the device satisfies one of the following conditions:

- Failure of the device would be reasonably likely to have serious adverse health consequences.
- The device is intended to be implanted for more than one year.
- The device is intended to sustain life outside a user facility.

The FDA only may order postmarket surveillance for up to three years without consent of the applicant.

Dispute resolution of scientific controversies (Section 404). By November 21, 1998, the FDA is theoretically required to set up a process, which an applicant can invoke, to review scientific controversies when no other process is available. It will include an appropriate advisory committee or scientific panel.

Reengineering the Center for Devices and Radiological Health (CDRH)

Modular review process for PMAs. In the future, the FDA will review the needed scientific data for a PMA in modules, as it becomes available. For example, all the data on animal testing would be reviewed, and if accepted, it would not be reexamined unless absolutely necessary. In addition to the other PMA modernization approaches discussed earlier, this allows companies to ensure that the proper scientific and regulatory foundation is developed and accepted as the clinical trials proceed, rather than being told at the end that there were problems with early data.

New multitype 510(k) approach. For Class I and II products that still require 510(k)s, the CDRH will establish a system of three types of 510(k): traditional, special, and abbreviated. The special 510(k) is for devices that have been modified, but the intended use has not changed, nor the fundamental science of the technology. A company needs only to file a declaration of conformity to design controls and a short summary of the changes, and the FDA will process the application within 30 days. For a new device, if a manufacturer uses special controls or conforms to a standard, it may submit a summary of the special controls or a declaration of conformity to the standard to get an abbreviated 510(k).

Appendix F: Pedicle Screw Product Liability Situation

As with all medical devices, product liability and product liability insurance can affect the performance of a company, even with proper regulatory approvals. Specifically, in the spinal device market there has been a significant amount of litigation activity regarding the use of pedicle screws to attach implants (rods) to the spine to promote fusion. Thus far, the plaintiffs have not been very successful.

Why Use Pedicle Screws?

Use of pedicle screws has become the standard of care for many noncage fusion procedures because of better results and proven safety. Prior to the use of pedicle screw-mounted implants, fusion was accomplished with either no instrumentation or using hooks and wire. Rates of fusion are nearly 90% using pedicle screw implants, versus 70% for those without implants. According to the FDA, a landmark study, *The Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar and Sacral Fusions,* validated the safety and efficacy of this approach. The study included 3,498 patients operated on by 314 surgeons. In addition, there have been more than 200 other peer-reviewed articles documenting the safety and efficacy of this approach. Lastly, less than 1% of implants that use pedicle screws have failed, out of more than 300,000 cases.

Pedicle Screw Litigation

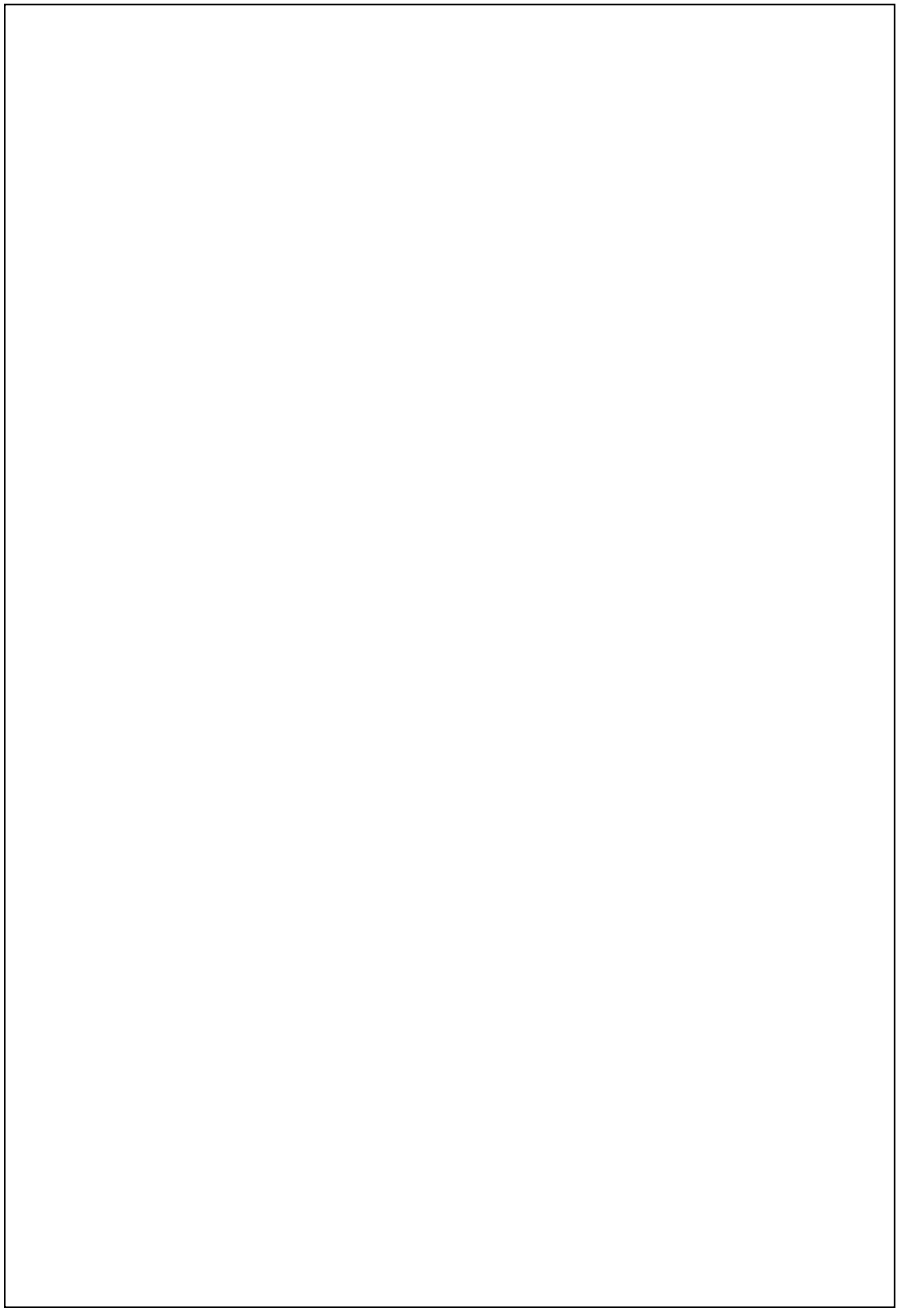
In 1994, SDG, along with other spinal implant companies, was named in a class-action product liability lawsuit, alleging that patients were injured by spinal implants, specifically pedicle screws that the company manufactured. In February 1995, Judge Bechtle denied class certification for the suits, while he still remained the coordinator of the individual cases. He subsequently dismissed all conspiracy and fraud claims without prejudice on procedural grounds.

In December 1996, AcroMed, SDG's largest competitor, established a $100 million settlement fund to settle the claims against it. AcroMed formally submitted a class settlement agreement to Judge Bechtle in January 1997 for a ruling on the fairness, adequacy, and reasonableness of this proposed settlement. Judge Bechtle approved the $100 million settlement in October 1997.

SDG has taken a different approach than AcroMed. In January 1997, SDG took a pretax charge of $50 million to cover the uninsured costs relating to the product liability lawsuits, including the costs to continue to defend against them. As of March 31, $11.5 million has been used. This approach has received praise from both the spine surgeons, as well as the medical societies still involved in the litigation. Both parties support this path, as they view personal injury litigation as a serious danger to their income (surgeons), free speech (medical societies), and independence (both). There is anecdotal evidence that this has contributed to SDG's share gains at AcroMed's expense.

For the time being, the costs of defending the claims have been paid by the companies that insure SDG. However, as is common practice, the insurance policies must be renewed each year, and there is no guarantee that such policies always will be available to the company. One of the insurance companies, Royal Surplus Lines, has an outstanding receivable of about $2.5 million.

As of December 1997, there were approximately 2,800 plaintiffs involved in product liability lawsuits, with additional 2,600 claimants in lawsuits alleging that SDG, along with competitors, conspired to illegally promote the use of spinal implant systems. For now, the court has allowed for the federal trial courts to consider each state's laws to determine if there were conspiracies among manufacturers, medical societies, and certain physicians to conceal relevant information from surgeons.



Appendix G: Glossary

360-degree fusion. Anterior plus posterior fusion.

510(k). A 510(k) is a premarketing notification submitted to the FDA to demonstrate that a medical device is as safe and effective and substantially equivalent to a legally marketed device that was on the United States market prior to 1976. The Food and Drug Modernization Act of 1997 allows for the FDA to reclassify new devices on the basis of potential risk.

AANS. American Association of Neurological Surgeons.

AAOS. The American Academy of Orthopaedic Surgeons.

ALIF. Anterior lumbar interbody fusion. Placement of bone or cages between vertebrae from an anterior approach.

Allograft. A graft transplanted between two different individuals of the same species (e.g., from cadavers).

Annulus. Outer portion of the disc that connects the vertebrae and comprises 18 layers of ligaments.

Anterior. Front-facing.

Anterior cervical plate. A metal plate used for internal fixation of cervical vertebrae. It is attached to the bone by screws inserted through holes in the plate.

Arthrodesis. An operation to stiffen a joint usually through bone fusion.

Autograft. A bone graft using the patient's own bone, usually harvested from the iliac crest of the hip.

Biceps. The large muscle at the front of the upper arm.

BMP. Bone morphogenic protein. Proteins found in demineralized bone matrix that participate in bone formation.

Bone graft. Bone transplanted from a donor site to a recipient site.

Bovine. From a cow.

Cancellous bone. Bone with a spongy or lattice-like structure. Also named trabecular bone.

CAS. Computer-assisted surgery.

Cervical vertebrae. The seven segments of the vertebral column located in the neck between the skull and the rib cage.

Cortical bone. Compact/dense bone.

CPT codes. Current procedural terminology. A set of codes published by the American Medical Association used for reimbursement purposes in the health care and insurance industries.

Cranium. The skull.

CT. Computed tomography. A diagnostic procedure using x-rays to produce computerized images of different parts of the body. The scan provides a detailed cross-section of the various tissues present, allowing physicians to examine characteristics of the head and body to detect abnormalities.

Degenerative disc disease. A deterioration in the structure or function of the disc.

Deltoid. The triangular muscle covering the shoulder joint.

Disc. A tough, elastic structure between the adjacent surfaces of the vertebrae, forming the connection between these segments and allowing for cushioning, movement, and shock absorption.

Discectomy. Surgical removal of intervertebral disc typically protruding (herniated) abnormally.

Discography. A diagnostic procedure used to determine the condition of a spinal disc. Using x-rays to verify needle location, a small amount of contrast liquid is injected into various cervical discs. If there is a tear, the liquid will leak out of the disc to surrounding areas and can be seen on an x-ray.

Dorsal. Pertaining to the back.

DRG. Diagnostic related groups. A system of codes used to group patients by diagnosis for reimbursement purposes.

Endoscopy. Examination of the interior of a canal or hollow viscus by means of a special instrument, such as an endoscope.

Facet joints. Vertebrae are connected to one another by a disc in the front and two facet joints in the back.

Flexion. A state of being bent or contracted.

GICD. Groupe International Cotrel-Dubousset

Harrington rods. The original hook-and-rod spinal system developed in the 1950s by Dr. Paul Harrington.

Herniated disc. An abnormal protrusion of an intervertebral disc.

Hydroxyapatite. A naturally occurring mineral that the crystal lattice of bones and teeth closely resemble.

Hypertrophy. An abnormal increase in size of a part or organ.

ICD-9 codes. International classification of diseases. A classification system that groups related disease entities and procedures for the reporting of statistical information.

IDE. Investigational device exemptions. These allow for new devices to be tested in human clinical trials.

Idiopathic. A disease of unknown origin.

Iliac crest. The highest part of the pelvis on each side is the thick iliac crest.

Kyphosis. An abnormal rearward curvature of the spine as viewed from the side.

Laminae. Two broad plates directed dorsally from the pedicles and providing a base for the spinous process.

Laminectomy. Removal of posterior bone (laminae) in the spine that surrounds the spinal cord. Often done in conjunction with a discectomy.

Lateral. Pertaining to the side.

Ligaments. A band of fibrous tissue that connects two or more bones or cartilages.

Lordosis. Natural curvature of the spine.

Lumbar vertebrae. The vertebrae, usually five in number, located in the lower back.

Medial. Relating to the middle.

Medical stationary status. The time from surgery to closure of insurance or worker's compensation claims.

Microscopy. Investigation of minute objects using a microscope.

MRI. Magnetic resonance imaging. An imaging technique that employs radio frequency waves and a strong magnetic field to produce clinically useful images.

Myelopathy. A spinal cord disorder.

NASS. North American Spine Society.

Nerve root. One of the two bundles of nerve fibers emerging from the spinal cord that join to form a single segmental spinal nerve.

Nucleus. Inner portion of the disc providing hydraulic support to cushion shocks while moving, consisting of a fluid-filled gel with a very high water content.

Orthosis. A brace or splint worn externally that prevents or assists movement of the spine or the limbs.

Osteoblast. A bone-forming cell.

Osteoclast. A cell that aids in the absorption and removal of bone.

Osteoconductive. Providing a suitable matrix or scaffold through which bone will form.

Osteogenic. Directly providing stem cells capable of making bone.

Osteoinductive. Inducing bone cell differentiation and growth through biological, chemical, mechanical, or physical means.

Osteoporosis. A reduction in the quantity of bone.

Pectoralis. The chest muscles.

Pedicle. A short, thick bone that projects backward from the body of a vertebra, which connects with the lamina on either side.

Pedicle fixation. Attaching to the pedicle.

Physiatrist. A doctor that specializes in physical or rehabilitation medicine.

PLIF. Posterior lumbar interbody fusion.

PMA. Premarket approval, the process of scientific and regulatory review to ensure the safely and effectiveness of all Class III (high-risk) and some Class II (moderate-risk) devices. An approved PMA application is, in effect, a license granted to the applicant for marketing a particular medical device, based on clinical trials proving both safety and efficacy.

Posterior. Rear-facing.

Pseudoarthrosis. A new, or false, joint arising at the site of an ununited fracture.

Quadriceps. The large muscle at the front of the thigh.

Radiculopathy. A disorder of the spinal nerve roots.

Sacrum. A triangular bone at the base of the spine, comprising five fused vertebrae, which is the segment of the vertebral column forming part of the pelvis.

Sciatica. Spine-related leg pain.

Scoliosis. An abnormal lateral curvature of the spine.

Spondylolisthesis. Anterior displacement of a lumbar vertebra on the vertebra below or sacrum.

Spondylosis. A stiffening or fixation of the vertebrae.

Spinal cord. The part of the central nervous system contained within the spinal canal, running from the base of the skull to the lower back.

Spinal fusion. An operative procedure in which the disc between two adjacent vertebrae is removed and the two vertebrae fused together.

Spinal stenosis. A narrowing or stricture of the spine.

Spinous process. Part of the vertebral arch that projects dorsally from the laminae.

SRS. Scoliosis Research Society.

Stereotactic (surgery). A precise method of destroying deep-seated brain structures located by use of three-dimensional coordinates.

Thoracic vertebrae. The 12 segments of the vertebral column between the neck and the abdomen that are attached to the rib cage.

Trabecular bone. Bone with a spongy or lattice-like structure. Also named cancellous bone.

Transverse process. The bony structures on each side of the spine that project laterally from the point where the laminae join the pedicles.

Triceps. The large muscle running along the back of the upper arm.

Vertebra. Any of the single bones or segments of the spinal column.

Vertebral foramen. Gap through which the spinal cord runs.

Xenograft. A graft transferred from an animal of one species to one of another species.