Symmetry Medical Inc.
Form S-1/A
December 06, 2004
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As filed with the Securities and Exchange Commission on December 6, 2004.

Registration No. 333-116038

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 6

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

SYMMETRY MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware	**3842**	**35-1996126**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

220 West Market Street

Warsaw, Indiana 46580

Telephone: (574) 268-2252

Telecopy: (574) 267-4551

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Brian Moore

President and Chief Executive Officer

Symmetry Medical Inc.

220 West Market Street

Warsaw, Indiana 46580

Telephone: (574) 268-2252

Telecopy: (574) 267-4551

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale of the securities to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	No. of Shares to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price (1) (2)	Amount of Registration Fee
Common Stock, par value $0.0001 per share	9,200,000	$ 15.00	$ 138,000,000	$ 17,485(3)

(1) Includes 1,200,000 shares that the underwriters have the option to purchase to cover over-allotments, if any.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(a) under the Securities Act.
(3) Previously paid by the Registrant.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the

Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED DECEMBER 6, 2004

Prospectus

8,000,000 Shares

Common Stock

Symmetry Medical Inc. is offering 8,000,000 shares of common stock. This is our initial public offering, and no public market currently exists for our shares. We anticipate that the initial public offering price will be between $13.00 and $15.00 per share. After the offering, the market price for our shares may be outside this range.

Our common stock has been approved for listing, subject to official notice of issuance, on the New York Stock Exchange under the symbol SMA.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 9.

	Per Share	Total
Offering price	$	$
Discount and commissions to underwriters	$	$
Offering proceeds to Symmetry Medical, before expenses	$	$

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

We have granted the underwriters the right to purchase up to 1,200,000 additional shares of common stock to cover any over-allotments. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares of common stock to investors on or about , 2004.

Banc of America Securities LLC **Credit Suisse First Boston**

Piper Jaffray **Wachovia Securities**

, 2004

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

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Financial Information

We operate on a 52- or 53- week year ending on the Saturday closest to December 31. Our fiscal years 1999, 2000, 2001, 2002 and 2003 ended on January 1, 2000, December 30, 2000, December 29, 2001, December 28, 2002 and January 3, 2004, respectively. Our fiscal years in 2000, 2001 and 2002 contained 52 weeks and our 1999 and 2003 fiscal years contained 53 weeks. Fiscal years are identified in this prospectus according to the calendar year that they most accurately represent. For example, the fiscal year ended January 3, 2004 is referred to herein as fiscal 2003 or fiscal year 2003. The first quarter of fiscal 2003 ended on March 29, 2003, and contained 13 weeks and the first quarter of fiscal 2004 ended on April 3, 2004 and contained 13 weeks. The second quarter of fiscal 2003 ended on June 28, 2003, and contained 13 weeks and the second quarter of fiscal 2004 ended on July 3, 2004 and contained 13 weeks. The third quarter of fiscal 2003 ended on October 4, 2003, and contained 14 weeks and the third quarter of fiscal 2004 ended on October 2, 2004 and contained 13 weeks.

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SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including the section entitled Risk Factors and the consolidated financial statements and accompanying notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, as used in this prospectus (i) the terms Symmetry, Symmetry Medical, we, us and our refer to Symmetry Medical Inc., a Delaware corporation, and all of its consolidated subsidiaries and (ii) the term Mettis refers to Mettis (UK) Limited, a United Kingdom corporation, and its consolidated subsidiaries, which we acquired on June 11, 2003. Unless the context otherwise requires, all pro forma data presented gives effect to the Mettis acquisition as if it occurred at the beginning of fiscal year 2003. Our statement of operations data for fiscal year 2003 only includes the results of Mettis since its acquisition date.

Our Business

We are the world s largest independent provider of implants and related instruments and cases to orthopedic device manufacturers. We also design, develop and produce these products for companies in other segments of the medical device market, including the dental, osteobiologic and endoscopy sectors, and we provide limited specialized products and services to non-healthcare markets, such as the aerospace market. Through our Total Solutions approach, we offer our customers a broad range of products, as well as comprehensive services and production capabilities to help them bring their implant systems to market quickly and efficiently. We believe that our Total Solutions approach will provide us with a competitive advantage in the market place.

We market our Total Solutions approach through our experienced sales force that operates in the United States, Europe and Japan. During fiscal year 2003, we generated pro forma revenues of $158.4 million, serving approximately 500 customers, including 72 new customers added during the year. Our broad customer base includes every major orthopedic device company, such as Biomet Inc., DePuy Inc. (a subsidiary of Johnson & Johnson), Kyocera Corporation, Medtronic Sofamor Danek, Smith & Nephew plc, Stryker Corporation, Synthes, Inc. (formerly Synthes-Stratec, Inc.) and Zimmer Holdings, Inc. We typically serve several product teams and facilities within each of our largest customers, and during the nine months ended October 2, 2004 and fiscal 2003, no single customer represented more than 22.6% of our revenue.

We offer a broad range of products in the following categories:

- implants, including forged, cast and machined products for the global orthopedic device market, which represented 36.3% and 27.3% of our revenue in the nine months ended October 2, 2004 and fiscal 2003, respectively;
- instruments used in the placement and removal of orthopedic implants and in other surgical procedures, which represented 33.0% and 37.4% of our revenue in the nine months ended October 2, 2004 and fiscal 2003, respectively;
- cases, including plastic, metal and hybrid cases used to organize, secure and transport medical devices for orthopedic and other surgical procedures, which represented 23.3% and 29.6 % of our revenue in the nine months ended October 2, 2004 and fiscal 2003, respectively; and
- other specialized products and services for non-healthcare markets, primarily the aerospace market, which represented 7.4% and 5.7 % of our revenue in the nine months ended October 2, 2004 and fiscal 2003, respectively.

We believe that we are well positioned to grow our business as a result of the expected expansion of the overall orthopedic device market. In addition, we believe that our Total Solutions approach provides us with significant opportunities to increase our sales by expanding the types of products and services we provide to our existing customers and by adding new customers in other medical device market segments.

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Market Opportunity

The global medical device market was estimated to be approximately $207 billion in 2003. The orthopedic device segment of the medical device market was estimated to be approximately $16 billion in 2003, and is expected to grow approximately 12% annually to greater than $25 billion by 2007.

Orthopedic devices principally consist of reconstructive implants used to replace or repair knees, hips, shoulders and other joints, as well as other orthopedic devices to repair bone fractures and the spine. There were approximately 1.5 million reconstructive orthopedic implant procedures performed globally in 2003, an increase of 13% over the previous year. We expect continued growth in the orthopedic device market to be driven by a number of trends including:

growing elderly population;

aging, affluent and active baby boomers ;

improving technologies that expand the market, including minimally invasive surgery;

successful clinical outcomes increasing patient confidence;

increasing patient awareness through orthopedic device companies direct marketing programs;

increasing volume of procedures to replace older implants (or revision procedures); and

developing international markets.

Our Total Solutions Approach

We believe that we have created a distinctive competitive position in the orthopedic device market based upon our Total Solutions approach. Our acquisition of Mettis in June 2003 expanded our products and services, enabling us to offer an integrated outsourcing solution. Our Total Solutions approach presents our customers with a broad range of products, as well as comprehensive design, engineering and project management services and state of the art production capabilities to help them bring their implant systems to market quickly and efficiently. We believe that our Total Solutions approach will be an increasing competitive advantage in the future. Our Total Solutions offering is based on:

Comprehensive services. We can support our customers new product offerings from product concept through market introduction and thereafter, by providing seamless design, engineering, prototyping and manufacturing services.

Single source for complete systems. We assist customers in developing new implants, and we design and produce instruments for implant-specific surgical procedures. We also provide customized cases that provide a secure, clearly labeled and well organized arrangement of instruments and devices.

Proprietary Symmetry instruments and cases. Our established lines of proprietary products allow our customers to complete their proprietary implant systems and bring them to market sooner.

Precision manufacturing expertise. Our extensive expertise and know-how enable us to produce large volumes of specialized products to our customers precise standards, which we believe makes us a supplier of choice to the largest orthopedic companies. Our core production competencies include net shaped forging, precision casting, thermo forming, precision sheet metal working and machining/finishing.

Quality and regulatory compliance. Our quality systems are based upon and in compliance with ISO requirements and, where applicable, United States Food and Drug Administration, or FDA, regulations. We believe our level of quality and regulatory compliance systems meet our customers expectations.

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Global reach. Our manufacturing capabilities in the United States and Europe allow us to offer single-source products and services to our multinational customers, and the geographic breadth of our experienced sales force effectively brings our Total Solutions approach to customers globally.

We believe that our Total Solutions approach offers a number of benefits to our customers, including:

Shorter time to market. Our design, engineering and prototyping skills, as well as our ability to transition seamlessly from product development to production of implants, instruments and cases, enable our customers to reduce time to market for their new products.

Reduced total product acquisition costs. Our comprehensive services, including design, engineering, prototyping, project management, production and inventory control, allow our customers to reduce their procurement costs and inventory levels, resulting in lower product acquisition costs.

Increased focus on marketing and research and development efforts. Our extensive production capabilities and comprehensive services offer a one-stop outsourcing solution and allow our customers to focus their resources on their design, development and marketing efforts.

Rationalized and reliable supply chain. Our scale, scope of products and services and Total Solutions approach allow large orthopedic companies to reduce the number of their independent suppliers and streamline their operations.

Enhanced product consistency on a global basis. Our extensive production platform, Total Solutions approach and international presence allow us to meet global demand for orthopedic devices, which is expected to increase.

Our Strategy

Our goal is to increase our share of the orthopedic device market and to leverage our strengths to expand in other medical device market segments. The key elements of our business strategy are to:

Develop strategic relationships with our customers through access to key decision makers. Our scale, scope of products and services and Total Solutions approach position us as an important partner to our customers. This position gives us access to key decision makers, with whom we intend to continue to build strategic relationships.

Capitalize on our Total Solutions approach. We believe that our Total Solutions approach shortens product development cycles, reduces design and manufacturing costs and simplifies purchasing and logistics, and we intend to aggressively market these benefits to our customers.

Increase sales to existing customers by cross selling products and services. Our cases are currently sold in nearly every segment of the medical device market. We believe that our diverse customer base offers us a natural entry point to new orthopedic and non-orthopedic customers for our implants and instruments.

Leverage manufacturing skills. We intend to leverage our investments in sophisticated equipment and manufacturing know-how to expand our existing customer relationships and to obtain new customers.

Increase new product development. Our Design and Development Center provides expertise and coordination for our design, engineering and prototyping services. We intend to use the dedicated expertise of our Design and Development Center to generate additional development projects with our customers and to expand our line of innovative and independently developed instruments and cases.

Collaborate with emerging companies. We believe that new and innovative medical device companies are creating a meaningful market presence and that our Total Solutions approach positions us to help these companies, many of which may have limited resources.

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History

We were established in 1976 as a supplier of instruments to orthopedic device manufacturers. During the 1990 s, we made several acquisitions, which expanded our customer base, enhanced our instrument product offerings and extended our product line to include cases designed for various medical devices and their related instruments. In October 2000, investment funds affiliated with Olympus Partners acquired control of our company through a recapitalization. In this transaction, the Olympus funds invested a total of $40.5 million in cash to acquire securities representing approximately 94% of our then outstanding voting stock. At that time, all of our stockholders entered into a stockholders agreement that provided for, among other things, customary tag-along, drag-along, preemptive and registration rights. On June 11, 2003, we acquired Mettis, a leading manufacturer of forged, cast and machined implants for the global orthopedic device market. This acquisition significantly expanded our product offerings and increased our European presence, allowing us to develop and manufacture a broad range of implants, instruments and cases for orthopedic device manufacturers on a global basis. In connection with the Mettis acquisition, the Olympus funds collectively invested an additional $63.0 million in equity and loaned us $8.0 million through the purchase of senior subordinated notes and stock purchase warrants. See Certain Relationships and Related Transactions.

Olympus Partners

Olympus Partners is a private asset management firm headquartered in Stamford, Connecticut, with assets under management of approximately $1.7 billion. Through its affiliated entity, OGP III, LLC, Olympus Partners is the general partner of Olympus Growth Fund III, L.P., a $505 million private equity fund dedicated to leveraged buyouts, recapitalizations and growth capital investments in middle-market companies throughout the United States and Western Europe. Since 1989, Olympus Partners has invested in more than 50 portfolio companies. Olympus Co-Investment Growth Fund III, L.P. and Olympus Executive Fund, L.P., funds affiliated with Olympus Partners, are also investors in our company both directly and indirectly through Olympus/Symmetry Holdings LLC, an affiliate of Olympus Partners that directly holds common stock and preferred stock of our company. For ease of reference, we sometimes refer to Olympus Growth Fund III, L.P., Olympus Co-Investment Growth Fund III, L.P., Olympus Executive Fund, L.P. and Olympus/Symmetry Holdings LLC in this prospectus as the Olympus funds. Prior to this offering, the Olympus funds beneficially owned an aggregate of approximately 82.1% of our common stock. See Principal Stockholders.

Risks Affecting Us

Our business is subject to numerous risks, as discussed more fully in the section entitled Risk Factors immediately following this prospectus summary. We depend on a limited number of customers, and if we lost a significant customer we could lose a material portion of our revenue. In addition, we operate in an industry that presents potential regulatory and product liability risks.

Corporate and Other Information

Our principal executive offices are located at 220 West Market Street, Warsaw, Indiana 46580, and our telephone number is (574) 268-2252. Our website is located at *www.symmetrymedical.com*. The information contained in, or that can be accessed through, our website is not part of this prospectus.

Symmetry Medical Inc.® and PolyVac®, among others, are registered trademarks of Symmetry Medical Inc. We have trademark rights in these marks in the United States and other countries. We have an application for trademark registration pending with respect to Total Solutions. This prospectus also refers to brand names, trademarks, service marks, and trade names of other companies and organizations, and these brand names, trademarks, service marks, and trade names are the property of their respective holders.

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Market, Ranking and Other Data

The data included in this prospectus regarding markets and ranking, including the size of certain markets and our position within these markets, are based on independent industry publications, security analyst research reports or other published industry sources and estimates based on our management s knowledge and experience in the markets in which we operate. Our management s estimates have been based on information obtained from our customers, distributors, suppliers, trade and business organizations and other contacts in the markets in which we operate. We believe these estimates to be accurate as of the date of this prospectus. However, this information may prove to be inaccurate because of the method by which some of the data were obtained or because this information cannot always be verified with complete certainty due to the limits on availability and reliability of raw data, the voluntary nature of the date gathering process and other limitations and uncertainties inherent in a survey of market size. Except as noted below, none of these publications, reports or other published industry sources were commissioned by us or prepared at our request and we have not sought or obtained the consent from any of these sources to include such market data in this prospectus.

Our belief that we are the world s largest independent developer of implants and related instruments and cases to orthopedic device manufacturers is supported by a report prepared in August 2004 by Knowledge Enterprises, Inc. at our request. Knowledge Enterprises is a strategic services firm focused on the global orthopedic market and has consented to our use of this report. This report identifies the key orthopedic suppliers and the total estimated 2003 orthopedic sales for such suppliers.

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The Offering

Common stock offered by Symmetry	8,000,000 shares
Common stock outstanding after this offering	32,792,318 shares
Use of proceeds	We intend to use approximately $36.4 million of the net proceeds from this offering to repay all of our existing subordinated indebtedness, of which $8.0 million is held by the Olympus funds, and approximately $45.0 million to repay a portion of our existing senior indebtedness. We also intend to use approximately $16.2 million of the net proceeds to repurchase a portion of our outstanding preferred stock and preferred stock warrants, approximately 93% of which are held by our affiliates. In the aggregate, we expect that our affiliates will receive approximately $23.0 million of the net proceeds from this offering, including $0.1 million that will be paid to some of our directors and senior officers. See Use of Proceeds and Certain Relationships and Related Transactions.
Proposed NYSE symbol	SMA

The number of shares of our common stock to be outstanding immediately after this offering excludes:

- 872,195 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $0.01 per share;
- 830,955 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $3.03 per share; and
- 2,293,526 shares of our common stock reserved for future issuance under our stock option and stock purchase plans.

Except as otherwise indicated, all of the information presented in this prospectus assumes the following:

- the repurchase of 13,005 shares of our outstanding preferred stock and warrants to purchase 452 shares of our preferred stock, approximately 93% of which are held by our affiliates, including 11,000 shares and warrants held by the Olympus funds, in connection with this offering;
- the conversion of the 88,583 shares of our outstanding preferred stock and warrants to purchase 3,078 shares of our preferred stock not repurchased into 9,002,832 shares of our common stock and warrants to purchase 286,818 shares of our common stock prior to the completion of the offering;
- the effectiveness of a 7.241-for-1 stock split of our common stock, which will occur prior to the offering;

an initial public offering price of $14.00 per share, the mid-point of the range set forth on the cover page of this prospectus;

the effectiveness of our restated certificate of incorporation and restated by-laws, which will become effective prior to the completion of the offering; and

no exercise of the underwriters over-allotment option.

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Summary Consolidated Financial Data

The following tables summarize our consolidated financial data for the periods presented. We have derived the summary consolidated financial data as of and for fiscal years 2001, 2002 and 2003 from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated financial statements as of and for fiscal years 2002 and 2003 have been audited by Ernst & Young LLP, and our consolidated financial statements as of and for fiscal year 2001 have been audited by Arthur Andersen LLP. For more information, see Experts. The financial data as of October 2, 2004 and for the nine months ended October 4, 2003 and October 2, 2004, are derived from our unaudited consolidated financial statements, which in the opinion of management, contain all adjustments necessary for a fair presentation of the consolidated financial data. Operating results for these periods are not necessarily indicative of the results of operations for a full year.

The summary pro forma as adjusted consolidated statement of operations data for the fiscal year 2003 and nine months ended October 4, 2003 give effect to the Mettis acquisition, the sale of 8,000,000 shares of our common stock and the application of the net proceeds therefrom as described under Use of Proceeds, the conversion of all of our remaining shares of preferred stock into common stock and the refinancing of our remaining senior indebtedness under a new senior credit facility as if such transactions occurred on December 29, 2002. The summary pro forma as adjusted consolidated statements of operations data for the nine months ended October 2, 2004 give effect to the same transactions, other than the Mettis acquisition, which is already reflected in such financial data.

You should read the following information together with the information under Selected Consolidated Financial Data, Unaudited Pro Forma Consolidated Statement of Operations, Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and the related notes included elsewhere in this prospectus.

	Fiscal Year				(unaudited) Nine Months Ended			
	2001	2002	2003(1)	Pro Forma As Adjusted 2003	October 4, 2003	Pro Forma As Adjusted October 4, 2003	October 2, 2004	Pro Forma As Adjusted October 2, 2004
	(dollars in thousands, except share and per share data)							
Consolidated Statement of Operations Data:								
Revenue	$ 66,495	$ 65,395	$ 122,029	$ 158,355	$ 84,736	$ 121,062	$ 153,053	$ 153,053
Cost of revenue	48,205	47,859	86,124	112,389	59,011	85,276	108,363	108,363
Gross profit	18,290	17,536	35,905	45,966	25,725	35,786	44,690	44,690
Selling, general and administrative expenses	10,494	9,440	17,115	23,508	11,893	18,286	16,975	16,975
Operating income	7,796	8,096	18,790	22,458	13,832	17,500	27,715	27,715
Interest expense	5,070	4,968	10,172	5,102	6,607	4,116	10,852	4,244
Loss on debt extinguishment(2)			1,436	1,436	1,436	1,436		
Interest rate swap valuation(3)	847	979	(1,358)	(1,272)	(857)	(771)	(809)	(809)
Other expense (income)	290	(42)	(374)	(411)	(171)	(208)	(230)	(230)
	1,589	2,191	8,914	17,603	6,817	12,927	17,902	24,510

Income (loss) before income taxes and cumulative effect of accounting change								
Income tax expense	1,400	841	3,009	5,949	2,302	4,371	6,108	8,361
Net income (loss) before cumulative effect of accounting change	189	1,350	5,905	11,654	4,515	8,556	11,794	16,149
Cumulative effect of accounting change(4)	(293)	(1,146)						
Net income (loss)	(104)	204	5,905	11,654	4,515	8,556	11,794	16,149

Financial data continues on the next page

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	Fiscal Year				(unaudited) Nine Months Ended			
	2001	2002	2003(1)	Pro Forma As Adjusted 2003	October 4, 2003	Pro Forma As Adjusted October 4, 2003	October 2, 2004	Pro Forma As Adjusted October 2, 2004
Preferred stock dividends	(3,185)	(4,410)	(7,028)		(4,757)		(7,069)	
Net income (loss) applicable to common shareholders	$ (3,289)	$ (4,206)	$ (1,123)	$ 11,654	$ (242)	$ 8,556	$ 4,725	$ 16,149
Net income (loss) per share:								
Basic	$ (0.48)	$ (0.61)	$ (0.10)	$ 0.36	$ (0.02)	$ 0.26	$ 0.30	$ 0.49
Diluted	(0.48)	(0.61)	(0.10)	0.34	(0.02)	0.25	0.28	0.47
Weighted average common shares and equivalent shares outstanding:								
Basic	6,854,736	6,905,800	11,797,842	32,792,318	9,699,423	32,792,318	15,789,486	32,792,318
Diluted	6,854,736	6,905,800	11,797,842	34,093,599	9,699,423	34,093,599	16,616,212	34,093,599

	As of October 2, 2004	
	Actual	As Adjusted (5)
	(dollars in thousands) (unaudited)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 1,980	$ 1,980
Working capital	37,425	41,150
Total assets	287,252	283,902
Long-term debt and capital lease obligations less current portion	128,740	57,009
Total shareholders equity	112,330	184,434

(1) Includes the results of Mettis since its acquisition on June 11, 2003.

(2) In fiscal 2003, we refinanced substantially all of our existing indebtedness as part of the financing of the acquisition of Mettis, resulting in a loss on debt extinguishment of $1,436.

(3) We enter into interest rate swap agreements to offset against changes in interest rates on our variable rate long-term debt. In accordance with Statement of Financial Accounting Standards (SFAS) No. 133, as amended, *Accounting for Derivative Instruments and Hedging Activities,* these agreements do not qualify for hedge accounting and accordingly, changes in the fair market value of these agreements are recorded each period in earnings.

(4) For fiscal 2001, reflects the cumulative effect of change in accounting principles resulting in the adoption of SFAS No. 133. For fiscal 2002, reflects a write-off of goodwill in connection with the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets.* Upon completion of the adoption of SFAS No. 142, we determined that the fair market value of the goodwill was lower than book value for one reporting unit, which resulted in an impairment charge.

(5) The As Adjusted column in the consolidated balance sheet data as of October 2, 2004 gives effect to the sale of 8,000,000 shares of our common stock and the application of the net proceeds therefrom as described under Use of Proceeds, the conversion of our outstanding shares of preferred stock not repurchased into 9,002,832 shares of our common stock and the refinancing of our remaining senior indebtedness under a new senior credit facility.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information in this prospectus, before making a decision to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and our future growth prospects could suffer. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks Related to Our Business

We depend heavily on sales to our significant customers, and our business could be adversely affected if any of them reduced or terminated its purchases from us.

A limited number of large orthopedic device manufacturers, all of whom are our customers, control the predominate share of the orthopedic device market. We depend heavily on sales to these large companies. Sales to our ten largest customers represented approximately 77.7% and 68.3% of our revenue in the nine months ended October 2, 2004 and fiscal 2003, respectively. Our four largest customers accounted for approximately 22.6%, 15.2%, 14.7% and 10.3% of our revenue in the nine months ended October 2, 2004 and our three largest customers accounted for approximately 19.5%, 14.7% and 10.5% of our revenue in fiscal 2003.

We expect that we will continue to depend on a limited number of large companies for a significant portion of our revenue. In addition, our customer base could become more concentrated if, among other things, there is further consolidation among orthopedic device manufacturers. If a significant customer reduces or delays orders from us, terminates its relationship with us or fails to pay its obligations to us, our revenues could decrease significantly.

If we are unable to continue to improve our products and to develop new products, we may experience a decrease in demand for our products or our products could become obsolete, and our business would suffer.

We sell our products to customers in markets that are characterized by technological change, product innovation and evolving industry standards. We are continually engaged in product development and improvement programs, both in collaboration with our customers and independently. Our customers may engage in additional in-house development and manufacturing, and we may be unable to compete effectively with our independent competitors, unless we can continue to develop and assist our customers in developing innovative products. Our competitors product development capabilities could become more effective than ours, and their new products may get to market before our products, may be more effective or less expensive than our products or render our products obsolete. If one or more of these events were to occur, our business, financial condition and results of operation could be adversely affected. See Business Competition for more information about our principal competitors.

We face competition from our customers in-house capabilities, established independent suppliers and potential new market entrants, and if we lose customers it could have an adverse effect on our revenue and operating results.

Our customers have varying degrees of development and manufacturing capabilities and one or more of them may seek to expand their in-house capabilities in the future. Many of our customers are larger and have greater financial and other resources than we do and can commit significant resources to product development and manufacturing. Most of our independent competitors are smaller companies, many of which have close customer relationships and either a low cost structure or highly specialized design or production capabilities. Our independent competitors may consolidate and some of our current and future competitors, either alone or in conjunction with their respective parent corporate groups, may have financial resources and research and development, sales and marketing and manufacturing capabilities or brand recognition that are greater than ours. In addition, the innovative nature of our markets may attract new entrants to the field. Our products may not be able to compete successfully with the products of other companies, which could result in the loss of customers and, as a result, decreased revenue and operating results.

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If product liability lawsuits are brought against us or our customers our business may be harmed.

The manufacture and sale of our healthcare and other products, including our aerospace products, expose us to potential product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design or manufacturing flaws in, our products, or use of our products with components or systems not manufactured by us. Future product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time or money in litigation or otherwise require us to pay significant damages, which could adversely affect our earnings and financial condition.

We carry product liability insurance which is limited in scope and amount and may not be adequate to protect us against product liability claims that arise in the future. We may be unable to maintain this insurance at reasonable costs and on reasonable terms, if at all.

Our business strategy is based on certain assumptions about the orthopedic device market and the acceptance by our customers of our Total Solutions offering, which, if incorrect, may adversely affect our growth and profitability.

We believe that the aging of the general population and increasingly active lifestyles and other trends in the industry will increase the need for orthopedic implant products, which we expect to increase demand for our products. Our expectations regarding demand for our products could materially differ from actual demand if our assumptions regarding these trends and continued acceptance of our products by orthopedic device manufacturers and the end-user market prove to be incorrect.

Prior to our acquisition of Mettis we provided instruments and cases. The acquisition of Mettis, on June 11, 2003, enabled us to offer our customers complete implant systems implants, instruments and cases. Our revenue to date have been derived primarily from the sale of implants, instruments and cases separately, or instruments and cases together, and we have derived relatively little revenue from sales of our Total Solutions offering. We cannot assure you that we will realize the expected benefits of our Total Solutions offering. Customers may not embrace our Total Solutions approach for a number of reasons, including a desire to maintain relationships with multiple outside suppliers or to rely on their in-house capabilities to develop and produce significant elements of their implant systems. In addition, we may not effectively implement our Total Solutions approach, including by not effectively managing our marketing, design, development or manufacturing activities across multiple product lines. Finally, if our competitors successfully replicate our products and services, then our Total Solutions approach may not provide us with a competitive advantage in the market. If we do not realize the expected benefits of our Total Solutions approach, we may not achieve our growth and profit goals.

Our operating results are subject to significant potential fluctuation and you should not rely on historical results as an indication of our future results.

Our operating results have fluctuated in the past and may vary significantly from quarter to quarter or year to year in the future due to a combination of factors, many of which are beyond our control. These factors include:

- the timing of significant orders and shipments, including the effects of changes in inventory management practices by our customers;

the number, timing and significance of new products and product introductions and enhancements by us, our customers and our competitors;

changes in pricing policies by us and our competitors;

changes in treatment practices;

restrictions and delays caused by regulatory review of our customers products;

recalls of our customers products;

availability and cost of raw materials; and

general economic factors.

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Our recent acquisition of Mettis may make it more difficult for us to evaluate and predict our future operating performance because our historical results of operations as a combined entity are limited and our audited financial statements only reflect the operations of Mettis since we acquired it in June 2003. Consequently, our historical results of operations may not give you an accurate indication of how we, together with the former Mettis operations, will perform in the future.

Our quarterly revenue and operating results may vary significantly in the future and period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indications of our future performance. We cannot assure you that our revenue will increase or be sustained in future periods or that we will be profitable in any future period. Any shortfalls in revenue or earnings from levels expected by securities or industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

If we do not retain key individuals and retain and attract skilled manufacturing workers, we may not be able to operate successfully, and we may not be able to meet our strategic objectives.

Our success depends in part upon the retention of key managerial, sales and technical personnel, particularly skilled manufacturing workers. We compete for such personnel with other companies and other organizations, many of which are larger and have greater name recognition and financial and other resources than we do. There can be no assurance that we will be successful in retaining our current personnel or in hiring or retaining qualified personnel in the future. The loss of key personnel or the inability to hire or retain qualified personnel in the future could have a material adverse effect on our ability to operate successfully.

We compete with numerous precision manufacturing companies to attract and retain qualified and highly skilled manufacturing employees. Our Warsaw, Indiana facilities, in particular, face significant competition, including from certain of our customers and other companies located in or near Warsaw that are larger and have greater financial and other resources than we do, for skilled production employees. If we are not able to retain and attract skilled manufacturing employees, we may be unable to support our anticipated growth, which could adversely affect our profitability.

A significant shift in technologies or methods used in the treatment of damaged or diseased bone and tissue could make our products obsolete or less attractive.

The development of new technologies could reduce demand for our products. For example, pharmaceutical advances could result in non-surgical treatments gaining more widespread acceptance as a viable alternative to orthopedic implants. The emergence of new biological tissue-based or synthetic materials to regenerate damaged or diseased bone and to repair damaged tissue could increasingly minimize or delay the need for implant surgery and provide other biological alternatives to orthopedic implants. New surgical procedures could diminish demand for our instruments. A significant shift in technologies or methods used in the treatment of damaged or diseased bone and tissue could adversely affect demand for our products.

We depend on various third party suppliers, and in some cases a single third party supplier, for key components and raw materials used in our manufacturing processes and the loss of these sources could harm our business.

We use a number of raw materials, including titanium, cobalt chrome, stainless steel and nickel alloys, and various other components in our products. Although we generally believe these materials are readily available from multiple sources, from time to time we rely on a limited number of suppliers and in some cases on a single source vendor. For example, we obtain patented Radel R plastic, which is designed to withstand intense heat produced during frequent sterilizations, for use in our instrument handles and plastic cases from a single supplier. Any supply interruption in a limited or sole-sourced component or raw material could materially harm our ability

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to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms if at all. This could interrupt our business or reduce the quality of our products.

If we are unable to manage changes in our business and our anticipated growth, our business could be harmed.

Our acquisition of Mettis on June 11, 2003 significantly increased the size and scope of our operations. Our business has continued to grow at a fast pace since the acquisition, and we believe we will continue to grow at a significant rate. Rapid growth of our business may place a strain on our managerial, operational and financial resources and systems. We are still in the process of completing our integration of Mettis business, and we cannot assure you that we will be successful in our integration efforts. We are also currently implementing new management information systems to assist us in consolidating our enterprise-wide operating and financial performance information. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. Any failure by us to implement our new management information systems, to integrate Mettis successfully, to develop our management, expand our work force or otherwise manage our growth effectively could have an adverse effect on our ability to achieve our business strategy. Our growth may be impaired if we are unable to meet the demands of our customers, which could result in our customers turning to alternative suppliers.

We require a significant amount of cash to service our indebtedness, which reduces the cash available to finance our organic growth and strategic acquisitions, alliances and collaborations.

We have a significant amount of indebtedness. As of October 2, 2004, on an as adjusted basis giving effect to this offering and the application of proceeds herefrom, our total indebtedness, including current maturities, would have been $62.7 million, and we would have been able to borrow an additional $24.9 million under our new senior credit facility that we will enter into in connection with this offering. As of October 2, 2004, on an as adjusted basis, our required debt service obligations under the new senior credit facility would have been $3.5 million, $5.2 million, $7.0 million, $8.8 million and $25.6 million during the following five fiscal years, respectively.

Our indebtedness could:

- make us more vulnerable to unfavorable economic conditions;
- make it more difficult to obtain additional financing in the future for working capital, capital expenditures or other general corporate purposes;
- require us to dedicate or reserve a large portion of our cash flow from operations for making payments on our indebtedness, which would prevent us from using it for other purposes;
- make us susceptible to fluctuations in market interest rates that affect the cost of our borrowings to the extent that our variable rate debt is not covered by interest rate derivative agreements; and
- make it more difficult to pursue strategic acquisitions, alliances and collaborations.

Our ability to service our indebtedness will depend on our future performance, which will be affected by prevailing economic conditions and financial, business, regulatory and other factors. Some of these factors are beyond our control. We believe that, based upon current levels of operations, we will be able to meet our debt service obligations when due. Significant assumptions underlie this belief including, among other things, that we will continue to be successful in implementing our business strategy and that there will be no material adverse developments in our business, liquidity or capital requirements. If we cannot generate sufficient cash flow from operations to service our indebtedness and to meet our other obligations and commitments, we might be required to refinance our debt or to dispose of assets to obtain funds for such purpose. We cannot assure you that refinancings or asset dispositions could be effected on a timely basis or on satisfactory terms, if at all, or would be permitted by the terms of our debt instruments.

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Our new senior credit facility will contain restrictions that limit our ability to pay dividends, incur additional debt, make acquisitions and make other investments.

In connection with this offering, we will enter into a new senior credit facility. The new senior credit facility will contain covenants that restrict our ability to make distributions to stockholders or other payments unless we satisfy certain financial tests and comply with various financial ratios. If we do not satisfy these tests or comply with these ratios, our creditors could declare a default under our debt instruments, and our indebtedness could be declared immediately due and payable. Our ability to comply with the provisions of our new senior credit facility may be affected by changes in economic or business conditions beyond our control.

Our new senior credit facility will also contain covenants that limit our ability to incur indebtedness, acquire other businesses, make capital expenditures and impose various other restrictions. These covenants could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities as they arise. We may be unable to comply with the forgoing financial ratios or covenants and, if we fail to do so, we may be unable to obtain waivers from our lenders. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

Our future capital needs are uncertain and we may need to raise additional funds in the future through debt or equity offerings. Our future capital requirements will depend on many factors, including:

- revenue generated by sales of our products;
- expenses incurred in manufacturing and selling our products;
- costs of developing new products or technologies;
- costs associated with capital expenditures;
- costs associated with our expansion;
- costs associated with regulatory compliance, including maintaining compliance with the quality system regulations imposed by the FDA; and
- the number and timing of acquisitions and other strategic transactions.

As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we

cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business strategy, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

We may not realize all of the sales expected from new product development programs.

We incur substantial expenses in developing and testing new products and related devices. The realization of additional revenue from new product development efforts is inherently subject to a number of important risks and uncertainties, including, directly or indirectly, end-user acceptance of the product, reimbursement approval of third-party payors such as Medicaid, Medicare and private insurers and, in some cases, FDA or comparable foreign regulatory approval of the product. In addition, our customers typically have no contractual requirement to purchase from us the products that we develop for their medical devices, and they could seek to have another supplier or in-house facilities manufacture products that we have developed for their medical devices. We also incur costs and make capital expenditures for new product development and production based upon certain estimates of production volumes for our existing and anticipated products. If the actual demand for our products is less than planned, our revenue and net income may decline.

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Our earnings could decline if we write off goodwill or intangible assets created as a result of our various acquisitions.

As a result of our various acquisitions we have accumulated a substantial amount of goodwill, amounting to $125.5 million as of October 2, 2004, or approximately 43.7% of our total assets as of such date. Goodwill and certain intangible assets are not amortized but rather are tested for impairment by us annually or more frequently if an event occurs or circumstances develop that would likely result in impairment. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition. We completed annual impairment tests as of October 1, 2003 and 2002 and concluded at those dates that no impairment of goodwill or intangible assets existed. During 2002, in connection with the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets,* we recognized impairment of approximately $1.1 million, which is reflected as a cumulative effect of an accounting change in our statement of operations. In the future, we could recognize impairment of our goodwill or other intangible assets and that impairment could result in a charge to our results of operation and have an adverse effect on our financial condition.

We had net losses in fiscal years 2000 and 2001, and we may not be profitable in the future.

We experienced net losses of $5.9 million and $0.1 million in fiscal years 2000 and 2001, respectively. These net losses resulted primarily from interest expense on funds borrowed in connection with our 2000 recapitalization and other expenses related to the recapitalization. There can be no assurance that we will be profitable in the future.

We anticipate incurring a pre-tax charge of approximately $9.3 million on the early extinguishment of debt in the quarter this offering is completed. As a result of this charge, it is likely we will report a net loss in that quarter.

If we are unable to protect our intellectual property and property rights, or are subject to intellectual property claims by third parties, our business could be harmed.

We rely on a combination of patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish and protect our proprietary rights to our technologies and products. We cannot guarantee that the steps we have taken or will take to protect our intellectual property rights will be adequate or that they will deter infringement, misappropriation or violation of our intellectual property. Litigation may be necessary to enforce our intellectual property rights and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expenses and may not adequately protect our intellectual property rights. In addition, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as U.S. laws, or at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. If our trade secrets become known, we may lose our competitive advantages.

We seek to protect our trade secrets, know-how and other unpatented proprietary technology, in part, with confidentiality agreements with our employees, independent distributors and customers. We cannot assure you, however, that:

these agreements will not be breached;

we will have adequate remedies for any breach; or

trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or independently developed by our competitors.

We hold licenses with third parties that are necessary to utilize certain technologies used in the design and manufacturing of some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business.

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In addition, third parties may claim that we are infringing, misappropriating or violating their intellectual property rights. We could be found to infringe those intellectual property rights, which could affect our ability to manufacture any affected product. In addition, any protracted litigation to defend or prosecute our intellectual property rights could drain our financial resources, divert the time and effort of our management and cause customers to delay or limit their purchases of the affected product until resolution of the litigation.

Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or using any of our products that incorporate the challenged intellectual property, which could adversely affect our revenue;
- obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and
- redesign or, in the case of trademark claims, rename our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Efforts to acquire other companies or product lines may divert our managerial resources away from our business operations, and if we complete an acquisition, we may incur or assume additional liabilities or experience integration problems.

We may seek to acquire businesses or product lines for various reasons, including to provide new product manufacturing and service capabilities, add new customers, increase penetration with existing customers or expand into new geographic markets. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These efforts could divert the attention of our management and key personnel from our business operations. If we complete acquisitions, we may also experience:

- difficulties in integrating any acquired companies, personnel and products into our existing business;
- delays in realizing the benefits of the acquired company or products;
- diversion of our management s time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated;
- difficulties in retaining key employees of the acquired business who are necessary to manage these businesses;

difficulties in maintaining uniform standards, controls, procedures and policies throughout our acquired companies; or

adverse customer reaction to the business combination.

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize acquisition expenses and acquired assets.

We are subject to certain risks associated with our foreign operations.

We have significant international operations, specifically in the United Kingdom and France. Certain risks are inherent in international operations, including:

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

foreign customers who may have longer payment cycles than customers in the United States;

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tax rates in certain foreign countries that may exceed those in the United States and foreign earnings that may be subject to withholding requirements or the imposition of tariffs, exchange controls or other restrictions including transfer pricing restrictions when products produced in one country are sold to an affiliated entity in another country;

general economic and political conditions in countries where we operate or where end-users of orthopedic devices reside may have an adverse effect on our operations;

difficulties associated with managing a large organization spread throughout various countries;

difficulties in enforcing intellectual property rights; and

required compliance with a variety of foreign laws and regulations.

If we continue to expand our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other risks. We cannot assure you that these and other factors will not have a material adverse effect on our international operations or our business as a whole.

Currency exchange rate fluctuations could have an adverse effect on our revenue and financial results.

We generate a significant portion of our revenue and incur a significant portion of our expenses in currencies other than U.S. dollars. To the extent that we are unable to match revenue received in foreign currencies with costs incurred in the same currency, exchange rate fluctuations in any such currency could have an adverse effect on our financial results.

We may be adversely affected as a result of the long lead times required for sales of certain new products.

We often compete for business at the beginning of the development of new medical devices or upon customer redesign of existing medical devices. Our customers generally must obtain clearance or approval from the FDA before commercially distributing their products. Unless exempt, a new medical device must be approved for commercial distribution in the United States by the FDA through the 510(k) pre-market Notification Process or, in some cases, through the more burdensome pre-market approval, or PMA, process. It generally takes three to six months from the date of submission to the FDA to obtain 510(k) clearance and one to three years from the date of submission to the FDA to obtain approval through the PMA process, but in each case may take significantly longer. This results in long lead times for some of our customers new products, which may make it difficult in the short term for us to obtain sales of new products to replace any unexpected decline in sales of existing products.

We may be adversely impacted by work stoppages and other labor matters.

Currently, none of our employees are unionized. However, from time to time some of our employees have attempted to unionize at two of our facilities. In addition, some of our orthopedic device customers have unionized work forces. While we have not experienced any adverse effects

from work stoppages or slow-downs at our customers facilities, work stoppages or slow-downs experienced by us, our suppliers or our customers or their suppliers could result in slow-downs or closures of facilities where our products are made or used. We cannot assure you that we will not encounter strikes, further unionization efforts or other types of conflicts with labor unions or our employees, which could have an adverse effect on our financial results.

If a natural or man-made disaster strikes one or more of our manufacturing facilities, we may be unable to manufacture certain products for a substantial amount of time and our revenue could decline.

We have ten manufacturing facilities, which are located in the United States, the United Kingdom and France. These facilities and the manufacturing equipment and personnel know-how that we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities

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may be affected by natural or man-made disasters. In the event that one of our facilities was affected by a disaster, we would be forced to attempt to shift production to our other manufacturing facilities or rely on third-party manufacturers, and our other facilities or a third-party manufacturer may not have the capability to effectively supply the affected products. Although we have insurance for damage to our property and the interruption of our business, this insurance may not be sufficient in scope or amount to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Our former independent public accountant, Arthur Andersen LLP, has ceased operations, and you may be unable to exercise effective remedies against it in any legal action.

Our former independent public accountant, Arthur Andersen LLP, provided us with auditing services for fiscal year 2001, including issuing an audit report with respect to our audited consolidated financial statements as of and for fiscal 2001 included elsewhere in this prospectus. On June 15, 2002, a jury in Houston, Texas found Arthur Andersen LLP guilty of a federal obstruction of justice charge arising from the federal government s investigation of Enron Corp. On August 31, 2002, Arthur Andersen LLP ceased practicing before the United States Securities and Exchange Commission, or SEC.

Arthur Andersen LLP has not reissued its audit report with respect to the audited consolidated financial statements included in this prospectus covered by such report. Furthermore, Arthur Andersen LLP has not consented to the inclusion or incorporation by reference of its audit report in the registration statement of which this prospectus forms a part or in any other filings we may make with the SEC. As a result, you may not have an effective remedy against Arthur Andersen LLP in connection with a material misstatement or omission with respect to our audited consolidated financial statements that are included elsewhere in this prospectus, the registration statement of which this prospectus forms a part or any other filing we may make with the SEC, including any claim under Sections 11 and 12 of the Securities Act of 1933, as amended, or the Securities Act. In addition, even if you were able to assert such a claim, as a result of its conviction and other lawsuits, Arthur Andersen LLP may fail or otherwise have insufficient assets to satisfy claims made by investors or by us that might arise under federal securities laws or otherwise relating to any alleged material misstatement or omission with respect to our audited consolidated financial statements. In addition, in connection with any future capital markets transaction in which we are required to include financial statements that were audited by Arthur Andersen LLP, as a result of the foregoing investors may elect not to participate in any such offering or, in the alternate, may require us to obtain a new audit with respect to previously audited financial statements. Consequently, our financing costs may increase or we may miss attractive capital market opportunities.

Risks Related to Our Industry

Orthopedic device manufacturers have significant leverage over their independent suppliers and consolidation could increase their leverage, which could result in the loss of customers or force us to reduce our prices.

We compete with many distributors and manufacturers to develop and supply implants, surgical instruments and cases to a limited number of large orthopedic device manufacturers. As a result, orthopedic device manufacturers have historically had significant leverage over their independent suppliers. For example, independent suppliers like us are subject to continuing pressure from the major orthopedic device manufacturers to reduce the cost of products and services while maintaining quality levels. In recent years, the medical device industry has experienced substantial consolidation. If the medical device industry, and the orthopedic device industry in particular, continues to consolidate, competition to provide products and services to orthopedic device manufacturers may become more intense. Orthopedic device manufacturers may seek to use their market power to negotiate price or other concessions for our products. If we are forced to reduce prices or if we lose customers because of competition, our revenue and results of operations would suffer.

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Our business is indirectly subject to healthcare industry cost containment measures that could result in reduced sales of or prices for our products.

Acceptance of our customers products by hospitals, outpatient centers and physicians depend on, among other things, reimbursement approval of third-party payors such as Medicaid, Medicare and private insurers. The continuing efforts of government, insurance companies and other payors of healthcare costs to contain or reduce those costs could lead to lower reimbursement rates or non-reimbursement for medical devices that use our products. If that were to occur, medical device manufacturers might insist that we lower prices on products related to the affected medical device or they might significantly reduce or eliminate their purchases from us of these related products, which could affect our profitability.

We and our customers are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture and price our products.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Some of our manufacturing processes are required to comply with quality systems regulations, including current good manufacturing practice requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Further, some of our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA or other agencies. Failure to comply with applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory agencies to grant future pre-market clearances or approvals, withdrawals or suspensions of current clearances or approvals and criminal prosecution.

In addition, orthopedic implants and other medical devices produced by our customers are subject to intensive regulation and potential pre-approval requirements by the FDA and similar international agencies that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations may be time consuming, burdensome and expensive for our customers and, indirectly, for us to the extent that our customers compliance depends on our operations. These regulations could negatively affect our customers abilities to sell their products, which in turn would adversely affect our ability to sell our products. This may result in higher than anticipated costs or lower than anticipated revenue.

The regulations that we and our customers are subject to are complex, change frequently and have tended to become more stringent over time.