

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON DECEMBER 11, 1997

REGISTRATION NOS. 333-

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

INTEGRATED SURGICAL SYSTEMS, INC.  
(NAME OF REGISTRANT IN ITS CHARTER)

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

68-0232575  
(I.R.S. EMPLOYER  
IDENTIFICATION NO.)

829 WEST STADIUM LANE  
SACRAMENTO, CALIFORNIA 95834  
TELEPHONE: (916) 646-3487  
TELECOPIER: (916) 646-4075  
(ADDRESS AND TELEPHONE NUMBER OF PRINCIPAL EXECUTIVE OFFICES)

DR. RAMESH C. TRIVEDI  
CHIEF EXECUTIVE OFFICER AND PRESIDENT  
INTEGRATED SURGICAL SYSTEMS, INC.  
829 WEST STADIUM LANE  
SACRAMENTO, CALIFORNIA 95834  
TELEPHONE: (916) 646-3487  
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(NAME, ADDRESS AND TELEPHONE NUMBER OF AGENT FOR SERVICE)

## COPIES TO:

JACK BECKER, ESQ.  
SNOW BECKER KRAUSS P.C.  
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NEW YORK, NEW YORK 10158-0125  
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## APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC:

As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, other than securities offered only in connection with dividend or interest reinvestment plans, please 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, please 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 delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

## CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED	PROPOSED MAXIMUM OFFERING PRICE PER SECURITY(1)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(1)	AMOUNT OF REGISTRATION FEE
Common Stock. \$.01 par value...	619,355	\$4.75(2)	\$2,941,936	\$867.87

(1) Estimated solely for the purpose of calculating the registration fee

pursuant to Rule 457 promulgated under the Securities Act of 1933.

(2) Calculated on the basis of the closing bid price of the Common Stock on the Nasdaq SmallCap Market on December 10, 1997.

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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 THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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INFORMATION CONTAINED HEREIN IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD NOR MAY OFFERS TO BUY BE ACCEPTED PRIOR TO THE TIME THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THESE SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

PRELIMINARY PROSPECTUS DATED DECEMBER 11, 1997  
SUBJECT TO COMPLETION

INTEGRATED SURGICAL SYSTEMS, INC.  
619,355 SHARES OF COMMON STOCK

This Prospectus relates to the sale of 619,355 shares (the "Shares") of common stock, par value \$.01 per share ("Common Stock"), of Integrated Surgical Systems, Inc., a Delaware corporation (the "Company"), by the selling stockholders named herein (the "Selling Stockholders"). See "Selling Stockholders." The Shares were acquired by the Selling Stockholders in exchange for securities of Innovative Medical Machines International, S.A. ("IMMI") in connection with the acquisition of IMMI by the Company on September 5, 1997.

The Selling Stockholders may sell the Shares, subject to specified volume limitations, from time to time directly to purchasers, or through broker-dealers who may receive compensation in the form of commissions or discounts from the Selling Stockholders or purchasers. Sales of the Shares may be effected by broker-dealers in ordinary brokerage transactions or block transactions on The Nasdaq SmallCap Market, the Pacific Exchange or the European Association of Securities Dealers Automated Quotation ("EASDAQ") system, through sales to one or more dealers who may resell as principals, in privately negotiated transactions or otherwise, at the market price prevailing at the time of sale, a price related to such prevailing market price or a negotiated price. Usual and customary or specifically negotiated brokerage fees may be paid by the Selling Stockholders in connection therewith. To the Company's knowledge, none of the Selling Stockholders has entered into any underwriting arrangements for the sale of the Shares. See "Plan of Distribution."

The Company will not receive any proceeds from the sale of the Shares by the Selling Stockholders.

The Common Stock is quoted on The Nasdaq SmallCap Market under the symbol "RDOC" and is listed on the Pacific Exchange under the symbol "ROB". The Common Stock also has been admitted for trading on EASDAQ under the symbol "RDOC". On December 10, 1997, the closing bid price of the Common Stock on The Nasdaq Smallcap Market was \$4 3/4 per share.

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THE SECURITIES OFFERED HEREBY ARE SPECULATIVE AND INVOLVE A HIGH DEGREE OF RISK. FOR A DESCRIPTION OF CERTAIN RISKS REGARDING AN INVESTMENT IN THE COMPANY, SEE "RISK FACTORS" COMMENCING ON PAGE 9.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

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The Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 (the "Securities Act") and any profits realized by them may be deemed to be underwriting commissions. Any broker-dealers that participate in the distribution of the Shares also may be deemed to be "underwriters", as defined in the Securities Act, and any commissions or discounts paid to them, or any profits realized by them upon the resale of any Shares purchased by them as principals, may be deemed to be underwriting commissions or discounts under the Securities Act. The sale of the Shares by the Selling Stockholders is subject to the prospectus delivery and other requirements of the Securities Act.

The Shares have been registered pursuant to registration rights granted to the Selling Stockholders. All costs, expenses and fees in connection with the registration of the Shares will be borne by the Company. The Selling Stockholders are responsible for the payment of brokerage commissions and discounts incurred in connection with the sale of the Shares. The Company has agreed to indemnify the Selling Stockholders against certain liabilities, including liabilities under the Securities Act.

THE DATE OF THIS PROSPECTUS IS DECEMBER , 1997

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CAUTIONARY STATEMENT FOR PURPOSES  
OF THE "SAFE HARBOR" PROVISIONS OF THE  
PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

THIS DOCUMENT SPECIFIES FORWARD-LOOKING STATEMENTS OF MANAGEMENT OF THE COMPANY, INCLUDING REVENUE PROJECTIONS. FORWARD-LOOKING STATEMENTS ARE STATEMENTS THAT ESTIMATE THE HAPPENING OF FUTURE EVENTS, ARE NOT BASED ON HISTORICAL FACT AND ARE "FORWARD-LOOKING STATEMENTS" WITHIN THE MEANING OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995. FORWARD-LOOKING STATEMENTS MAY BE IDENTIFIED BY THE USE OF FORWARD-LOOKING TERMINOLOGY SUCH AS "MAY", "WILL", "EXPECT", "ESTIMATE", "ANTICIPATE", "PROBABLE", "CONTINUE", OR SIMILAR TERMS, VARIATIONS OF THOSE TERMS OR THE NEGATIVE OF THOSE TERMS. THE "RISK FACTORS" SET FORTH IN THIS DOCUMENT CONSTITUTE CAUTIONARY STATEMENTS IDENTIFYING IMPORTANT FACTORS THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE IN THE FORWARD-LOOKING STATEMENT IDENTIFYING IMPORTANT FACTORS THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE IN THE FORWARD-LOOKING STATEMENTS. THE FORWARD-LOOKING STATEMENTS SPECIFIED IN THIS DOCUMENT HAVE BEEN COMPILED BY MANAGEMENT OF THE COMPANY ON THE BASIS OF ASSUMPTIONS MADE BY MANAGEMENT AND CONSIDERED BY MANAGEMENT TO BE REASONABLE. FUTURE OPERATING RESULTS OF THE COMPANY, HOWEVER, ARE IMPOSSIBLE TO PREDICT AND NO REPRESENTATION, GUARANTY, OR WARRANTY IS TO BE INFERRED FROM THOSE FORWARD-LOOKING STATEMENTS. THEREFORE, PROSPECTIVE PURCHASERS OF SHARES OF COMMON STOCK ARE URGED TO CONSULT WITH THEIR ADVISORS (THE OPINIONS OF WHICH MAY DIFFER FROM THOSE SPECIFIED IN THOSE FORWARD-LOOKING STATEMENTS) WITH RESPECT TO THOSE ASSUMPTIONS OR HYPOTHESES.

THE ASSUMPTIONS USED FOR PURPOSES OF THE FORWARD-LOOKING STATEMENTS SPECIFIED IN THIS DOCUMENT, INCLUDING THOSE REVENUE PROJECTIONS, REPRESENT ESTIMATES OF FUTURE EVENTS AND ARE SUBJECT TO UNCERTAINTY AS TO POSSIBLE CHANGES IN ECONOMIC, LEGISLATIVE, INDUSTRY, AND OTHER CIRCUMSTANCES. AS A RESULT, THE IDENTIFICATION AND INTERPRETATION OF DATA AND OTHER INFORMATION AND THEIR USE IN DEVELOPING AND SELECTING ASSUMPTIONS FROM AND AMONG REASONABLE ALTERNATIVES REQUIRE THE EXERCISE OF JUDGMENT. TO THE EXTENT THAT THE ASSUMED EVENTS DO NOT OCCUR, THE OUTCOME MAY VARY SUBSTANTIALLY FROM ANTICIPATED OR PROJECTED RESULTS, AND ACCORDINGLY, NO OPINION IS EXPRESSED ON THE ACHIEVABILITY OF THOSE FORWARD-LOOKING STATEMENTS, INCLUDING THOSE REVENUE PROJECTIONS.

THESE FORWARD-LOOKING STATEMENTS, INCLUDING THESE REVENUE PROJECTIONS, HAVE BEEN COMPILED AS OF THE DATE OF THIS DOCUMENT AND SHOULD BE EVALUATED WITH CONSIDERATION OF ANY CHANGES OCCURRING AFTER THE DATE OF THIS DOCUMENT. NO ASSURANCE CAN BE GIVEN THAT ANY OF THE ASSUMPTIONS RELATING TO THE FORWARD-LOOKING STATEMENTS SPECIFIED IN THIS DOCUMENT, INCLUDING THOSE REVENUE PROJECTIONS, ARE ACCURATE OR THAT THEY WILL PROVIDE TO BE APPLICABLE TO A PARTICULAR PURCHASER OF THE SHARES OF COMMON STOCK. IT IS THE RESPONSIBILITY OF THE PURCHASERS OF THE COMMON STOCK AND THEIR ADVISORS TO REVIEW THOSE FORWARD-LOOKING STATEMENTS, INCLUDING THOSE REVENUE PROJECTIONS TO CONSIDER THE ASSUMPTIONS ON WHICH THOSE FORWARD-LOOKING STATEMENTS ARE BASED AND TO ASCERTAIN THEIR REASONABLENESS.

NO DEALER, SALESMAN OR OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATION IN CONNECTION WITH THIS OFFERING OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS AND, IF GIVEN OR MADE, SUCH OTHER INFORMATION AND REPRESENTATIONS MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAD BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN JURISDICTIONS IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANYONE TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

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## AVAILABLE INFORMATION

The Company is subject to the reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), and, in accordance therewith, files, reports, proxy and information statements and other information with the Securities and Exchange Commission (the "Commission"). The Company has filed a Registration Statement on Form S-3 under the Securities Act with the Commission in Washington, D.C. with respect to the shares of Common Stock offered hereby. This Prospectus, which is part of the Registration Statement, does not contain all of the information set forth in the Registration Statement and the exhibits thereto. For further information with respect to the Company and the shares offered hereby, reference is made to the Registration Statement and such exhibits as well as the reports, proxy and information statements and other information filed under the Exchange Act, which may be inspected and copied at the Public Reference Section of the Commission at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549 and at the following regional offices: New York Regional Office, Suite 1300, 7 World Trade Center, New York, New York 10048, and Chicago Regional Office, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511, and copies of such material may also be obtained from the Public Reference Section of the Commission at prescribed rates. The Commission maintains a Web site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding registrants that file electronically.

## INFORMATION INCORPORATED BY REFERENCE

The following documents filed with the Commission are incorporated into this Prospectus by reference:

- (1) The Company's Prospectus dated November 14, 1997, filed pursuant to Rules 424(b)(1) and 430A promulgated under the Securities Act.
- (2) The Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1996.
- (3) The Company's Quarterly Reports on Form 10-QSB for the fiscal quarters ended March 31, 1997, June 30, 1997 and September 30, 1997, respectively.
- (4) The Company's Current Report on Form 8-K dated September 5, 1997, as amended.
- (5) The description of the Common Stock set forth in the Company's Registration Statement on Form 8-A (File No. 1-12471), filed pursuant to Section 12(b) of the Exchange Act, and any amendment or report filed for the purpose of updating such description.

All documents filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act subsequent to the date of this Prospectus and prior to the termination of the offering made hereby shall be deemed to be incorporated by reference herein and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Prospectus.

The Company will provide without charge to each person to whom a Prospectus is delivered upon written or oral request of such person, a copy of any documents incorporated herein by reference (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this Prospectus incorporates). Requests for copies of such documents should be directed to the Company, 829 West Stadium Lane, Sacramento, California 95834, Attention: Corporate Secretary, telephone (916)646-3487, fax (916)646-4075.

## PROSPECTUS SUMMARY

The following summary is qualified in its entirety by the more detailed information, financial statements and the notes thereto appearing elsewhere in, or incorporated by reference into, this Prospectus. Unless otherwise indicated or the context otherwise requires, (i) all references to the Company in this Prospectus include Integrated Surgical Systems, Inc., a Delaware corporation, and its wholly owned subsidiaries, except that information concerning the Company prior to September 5, 1997, does not include Innovative Medical Machines International, S.A. ("IMMI"), acquired by the Company on that date, and (ii) all share and per share data and information in this Prospectus relating to the number of shares of Common Stock outstanding give effect to a one-for-five reverse stock split with respect to the Company's capital stock effected on December 20, 1995, and a one-for-1.479586 reverse stock split with respect to the Common Stock effected on November 6, 1996.

## THE COMPANY

Integrated Surgical Systems, Inc. develops, assembles, markets and services image-directed, computer-controlled robotic products for surgical applications. The Company's principal products are the ROBODOC(R) Surgical Assistant System (the "ROBODOC System"), consisting of a computer-controlled surgical robot and the Company's ORTHODOC(R) Presurgical Planner (the "ORTHODOC"), and as a result of the acquisition of IMMI, the NeuroMate System, consisting of a computer controlled robotic arm, head stabilizer and monitor (the ROBODOC System and the NeuroMate System are sometimes referred to collectively as the "Systems").

The ROBODOC System has been used for primary total hip replacement ("THR") surgery on over 1,500 patients in Europe and the United States. The Company believes its "active" robotic system is the only available system that can accurately perform key segments of surgical procedures with precise tolerances generally not attainable by traditional manual surgical techniques. The ROBODOC System also allows the surgeon to prepare a preoperative plan specifically designed for the characteristics of the individual patient's anatomy. The technology for the ROBODOC System was initially developed at the University of California, Davis, in collaboration with International Business Machines Corporation ("IBM"). IBM has rights to acquire approximately 20% of the Common Stock on a fully diluted basis.

The ORTHODOC is a computer workstation that utilizes the Company's proprietary software for preoperative surgical planning. The ORTHODOC is included as part of the ROBODOC System, but is also planned to be marketed separately by the Company. The ORTHODOC converts computerized tomography ("CT") scan data of a patient's femur (i.e., thigh bone) into three-dimensional images, and through a graphical user interface allows the surgeon to examine the bone more thoroughly and to select the optimal implant for the patient using a built-in library of available implants. A tape of the planned surgical procedure, developed by the ORTHODOC, guides the surgical robot arm of the ROBODOC System to accurately mill a cavity in the bone, thus allowing the surgeon to properly orient and align the implant. Non-clinical scientific data published by scientists from the Company and IBM demonstrate that as a result of the precise milling of a cavity, the ROBODOC System achieves over 95% bone-to-implant contact, as compared to an average of 20% bone-to-implant contact when surgery is performed manually.

THR surgery involves the insertion of an implant or metal prosthesis into a cavity created in the patient's femur. The Company believes that precise fit and correct alignment of the implant within the femoral cavity are key factors in the long-term success of THR surgery. In conventional THR surgery, a bone cavity is cut in the shape of the implant manually with metal tools, and the surgical plan, including the selection of the size and shape of the implant, is generally formulated based upon patient data obtained from two-dimensional x-ray images of the patient's femur. Based upon clinical experience with the ROBODOC System to date in Europe, patients generally have become weight-bearing in a shorter period than generally experienced by patients who have had this surgery performed manually. In addition, clinical data obtained from trials in Europe and the United States indicates that intraoperative fractures have been dramatically reduced in THR surgeries performed with the ROBODOC System (no intraoperative fractures have resulted from THR surgeries performed with the ROBODOC System to date). The Company also believes fewer hip revision

surgeries (implant replacements) may be necessary for patients who have had primary THR surgery performed with the ROBODOC System, as compared to patients who have had this surgery performed manually.

The NeuroMate System has been used to perform over 1,500 neurosurgical procedures in Europe and Japan. The Company believes that the NeuroMate System, which uses its proprietary robotic arm design and control systems designed specifically for use in the operating room, is the only image-guided, computer-controlled stereotactic robot currently in use to precisely position and hold critical tools used in the performance of neurosurgical procedures. Stereotactic neurosurgery is a minimally invasive approach to operating on the brain. Because the brain is largely unexposed, it requires the surgeon to work without direct visualization of the brain itself. This is overcome by a thorough understanding of brain anatomy and by using a spatial coordinate system that allows the surgeon to "navigate" within the brain without directly visualizing it. Essentially, the coordinate space of the patient's brain is correlated to the patient's own CT, magnetic resonance (MR) or other images by using anatomical landmarks that are shared by the patient and the images. This is known as "registration" of the patient's coordinate space to the coordinate space of the images. Once this is accomplished, the patient's CT scan can be used to guide the surgeon to specific sites within the brain through small holes the surgeon has made in the cranium (i.e., not necessitating a craniotomy).

The Company is seeking to establish itself as a leading provider of innovative image-directed, computer-controlled robotic technologies worldwide, initially for orthopaedic and neurosurgical applications and subsequently for other surgical applications. The Company's business strategy over the next two years is to concentrate its marketing and sales efforts on selling the ROBODOC System throughout Europe and then Japan, subject to obtaining the requisite approval from the Japanese Ministry of Health, and selling the NeuroMate System throughout Europe, Japan and the United States. The Company will thereby attempt to establish an installed customer base in the United States, Europe, Japan and other foreign markets through the sale of its systems, and offer its customers separate software packages for each new application if, as and when developed by the Company. Consequently, the Company's customers would be able to use the ROBODOC System as the platform for performing a variety of orthopaedic surgical procedures, and the NeuroMate System as the platform for performing a variety of neurosurgical procedures, without incurring significant additional hardware costs. The Company also plans to further exploit its image-directed robotics technology by incorporating additional imaging modalities for presurgical planning, including ultrasound (which is less expensive than CT) and MRI (which, unlike CT, does not involve the risk of radiation).

The Company markets the ROBODOC System in Europe through direct marketing and arrangements with implant companies. The ROBODOC System satisfies the appropriate international standards for medical equipment and meets the requirements for the European conformity mark ("CE Mark"). The Company markets the NeuroMate through direct marketing in Europe and through its distributor in Japan. It is anticipated that marketing of the NeuroMate in the United States will commence in early 1998 through a combination of direct marketing and select distributors/agents. During the nine months ended September 30, 1997, the Company realized revenues of approximately \$2,818,000 from the commercial sales of the ROBODOC System (including related consumables) in Europe.

The Company has developed a software package, in collaboration with IBM and Johns Hopkins University, for surgery to replace loose or otherwise failed hip implants (the "hip revision application") using the ROBODOC System. The Company has completed clinical evaluations of the hip revision application in Europe and plans to commence marketing the software for the hip revision application to its customers in Europe in early 1998. The development of the hip revision application has been funded in part by a grant from the National Institute for Standards and Technology (Advanced Technology Program) of the United States Department of Commerce.

The ROBODOC System cannot be marketed in the United States until clearance or approval is obtained from the U.S. Food and Drug Administration ("FDA"). The Company previously announced its intention to submit a pre-market approval application ("PMA") to the FDA in late 1997 for approval to market the ROBODOC System in the United States. The Company currently is exploring a regulatory strategy that may allow the Company to pursue FDA clearance of the ROBODOC System through a 510(k) submission in lieu



of a PMA application, which would be a less onerous and lengthy regulatory path if such an approach were acceptable to the FDA. The Company is currently gathering and evaluating clinical and radiographic data from the U.S. clinical trial and European studies. Therefore, the submission of a 510(k) or PMA application will be delayed beyond the projected late 1997 date. There can be no assurance that the Company will obtain clearance or approval to market the ROBODOC System in the United States. See "Risk Factors -- Government Regulation."

The Company has received clearance from the FDA to sell the ORTHODOC in the United States, and intends to commence marketing the ORTHODOC in the United States in early 1998. See "Risk Factors -- Available Clinical Data; Risk Versus Benefit Issues" and "Risk Factors -- Government Regulation."

The NeuroMate System has received clearance from the FDA for marketing in the United States and from the Japanese Ministry of Health for marketing in Japan. It also satisfies the relevant provisions of the European Medical Device Directive for Class II Medical Devices, thus allowing the Company to apply the "CE Mark."

On November 20, 1997, the Company received net proceeds of approximately \$8,800,000 from the sale of 1,500,000 shares of Common Stock in an offering to European investors (the "European Offering") for which CA IB Investmentbank Aktiengesellschaft ("CA IB") was the lead manager and K-B Securities N.V. was co-manager.

The Company was incorporated under the laws of the State of Delaware on October 1, 1990. The Company's offices are located at 829 West Stadium Lane, Sacramento, California 95834, and its telephone number is (916) 646-3487.

#### THE OFFERING

Securities Offered.....	619,355 shares of Common Stock by the Selling Stockholders. See "Selling Stockholders" and "Plan of Distribution."
Common Stock Outstanding(1).....	5,490,811 shares of Common Stock.
Risk Factors.....	The securities offered hereby involve a high degree of risk. Only investors who can bear the loss of their entire investment should invest. See "Risk Factors."
Nasdaq SmallCap Market Symbol.....	RDOC
Pacific Exchange Symbol....	ROB
EASDAQ Symbol.....	RDOC
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(1) Does not include (i) 4,507,816 shares of Common Stock issuable upon the exercise of warrants at exercise prices ranging from \$.01 to \$8.34, and (ii) 1,216,542 shares of Common Stock issuable upon exercise of outstanding options granted pursuant to the Company's stock option plans at exercise prices ranging from \$0.07 to \$8.75 per share.	

## SUMMARY OF CONSOLIDATED FINANCIAL INFORMATION

The summary financial information set forth below is derived from and should be read in conjunction with the Company's consolidated financial statements and unaudited pro forma combined condensed financial statements, including the notes thereto, incorporated by reference into this Prospectus. The historical summary financial information set forth below includes the results of operations of IMMI for the period subsequent to its acquisition by the Company on September 5, 1997.

## STATEMENT OF OPERATIONS DATA:

	YEAR ENDED DECEMBER 31,		PRO FORMA COMBINED YEAR ENDED DECEMBER	NINE MONTHS ENDED SEPTEMBER 30,		PRO FORMA COMBINED NINE MONTHS ENDED
	1995	1996	31, 1996(2)	1996	1997	SEPTEMBER 30, 1997(2)
Net sales.....	\$ 174,521	\$ 2,280,311	\$ 2,727,621	\$ 1,748,065	\$ 2,818,262	\$ 3,438,323
Gross profit.....	104,342	1,396,159	1,642,587	1,083,086	1,701,685	2,034,145
Operating loss.....	(3,925,730)	(3,495,861)	(5,218,358)	(2,168,228)	(2,998,831)	(3,360,242)
Net loss.....	(4,053,528)	(3,448,829)	(5,176,800)	(2,122,377)	(2,851,419)	(3,153,217)
Net loss applicable to common stockholders.....	(4,989,853)	(3,448,829)	(5,176,800)	(2,122,377)	(2,851,419)	(3,153,217)
Net loss per common and common share equivalent.....	\$(1.19)	\$(0.79)	\$(1.04)	\$(0.48)	\$(0.83)	\$(0.78)
Shares used in per share calculations(1).....	4,178,877	4,373,947	4,993,302	4,377,679	3,422,703	4,042,058

## BALANCE SHEET DATA:

	SEPTEMBER 30, 1997	
	ACTUAL	PRO FORMA(3)
Working capital.....	\$ 2,648,744	\$ 11,475,367
Total assets.....	10,367,637	19,194,260
Accumulated deficit.....	(21,952,230)	(21,952,230)
Stockholders' equity.....	7,557,365	16,383,988

- (1) See Note 2 of notes to December 31, 1996 consolidated financial statements incorporated by reference into this Prospectus for an explanation of the determination of the number of shares used in computing net loss per share.
- (2) Gives effect to the acquisition of IMMI using the purchase method of accounting as of January 1, 1996 for statement of operations data. The pro forma information is presented for illustrative purposes only and may not be indicative of the results that would have been obtained had the transaction actually occurred on the date assumed nor is it necessarily indicative of the future combined results of operations. See the unaudited Pro Forma Combined Condensed Financial Statements incorporated by reference into this Prospectus.
- (3) Gives effect to the issuance and sale of 1,500,000 shares of Common Stock in the European Offering, and the receipt of the net proceeds thereof. Does not include 4,507,816 shares of Common Stock issuable upon exercise of outstanding warrants at exercise prices ranging from \$0.01 to \$8.34 per share, and (ii) 1,216,542 shares of Common Stock issuable upon exercise of outstanding options granted pursuant to the Company's stock option plans, at exercise prices ranging from \$0.07 to \$8.75 per share.

## RISK FACTORS

The shares of Common Stock offered hereby are speculative and involve a high degree of risk, including, but not limited to, the risk factors described below. Each prospective investor should carefully consider the following risk factors before making an investment decision.

**HISTORY OF LOSSES; ACCUMULATED DEFICIT; ANTICIPATED FUTURE LOSSES.** Since its inception, the Company has incurred losses. The Company incurred a net loss of approximately \$3,449,000 (on net sales of approximately \$2,280,000) for its fiscal year ended December 31, 1996 and a net loss of approximately \$4,054,000 (on net sales of approximately \$175,000) for its fiscal year ended December 31, 1995. In addition, the Company incurred a net loss of approximately \$2,851,000 (on net sales of approximately \$2,818,000) for the nine months ended September 30, 1997, as compared to a net loss of approximately \$2,122,000 (on net sales of approximately \$1,748,000), for the nine months ended September 30, 1996. IMMI also has incurred losses since its inception, including a net loss of approximately \$910,000 (on net sales of approximately \$447,000) for its fiscal year ended December 31, 1996, and a net loss of approximately \$27,000 (on net sales of approximately \$618,000) for the six months ended June 30, 1997, as compared to a net loss of approximately \$423,000 (on net sales of approximately \$147,000) for the six months ended June 30, 1996. At September 30, 1997, the Company's accumulated deficit was approximately \$21,952,000 and at June 30, 1997 IMMI's accumulated deficit was approximately \$1,605,000, in each case as a result of continuing losses. The Company expects to continue to incur operating losses until such time, if ever, as it derives significant revenues from the sale of its products. The Company's ability to operate profitably depends upon market acceptance of its orthopaedic and neurosurgical products, the development of an effective sales and marketing organization, and the development of new products and improvements to existing products. There can be no assurance that the Company will obtain FDA approval to market the ROBODOC System in the United States or that its products will achieve market acceptance in the United States, Europe and other foreign markets to generate sufficient revenues to become profitable. See "Risk Factors -- Dependence on Principal Product," "-- Uncertainty of Market Acceptance," "-- Available Clinical Data; Risk Versus Benefit Issues" and "-- Government Regulation."

**LIMITED OPERATING HISTORY.** Although the Company commenced operations in October 1990, its operations have consisted primarily of the development and clinical testing of the ORTHODOC and the ROBODOC System, the organization of its manufacturing facility, the hiring of key personnel and the formulation of a plan for marketing the ROBODOC System in Europe. Although commercial sales of the ROBODOC System have been made in Europe, the Company has engaged only in clinical testing of the ROBODOC System in the United States, and the Company's ability to market the ROBODOC System in the United States is dependent upon FDA approval. See "Risk Factors -- Government Regulation." Accordingly, the Company must be evaluated in light of the uncertainties, delays, difficulties and expenses commonly experienced by companies in the early operating stage, which generally include unanticipated problems and additional costs relating to the development and testing of products, product approval or clearance, regulatory compliance, commencement of production, product introduction and marketing, and competition. Many of these factors may be beyond the Company's control, including but not limited to unanticipated results of product tests requiring modification in product design, changes in applicable government regulations or the interpretation thereof, market acceptance of the Company's products and development of competing products by others. In addition, the Company's future performance also will be subject to other factors beyond the Company's control, including general economic conditions and conditions in the healthcare industry or targeted commercial markets. See "Risk Factors -- Dependence on Principal Product," "-- Uncertainty of Market Acceptance," "-- Competition," "-- Available Clinical Data; Risk Versus Benefit Issues" and "-- Government Regulation."

**LENGTHY SALES CYCLE.** Since the purchase of a ROBODOC System or NeuroMate System represents a significant capital expenditure for a customer, the placement of orders may be delayed due to customers' internal procedures to approve large capital expenditures. The Company anticipates that the period between initial contact of a customer for a System and submission of a purchase order by that customer could be as long as 9 to 12 months. Furthermore, the current lead time required by the supplier of the robot for either the ROBODOC System or the NeuroMate System is approximately four months after receipt of the order. Although the Company generally intends to require a deposit upon receipt of an order for a System, the

Company may be required to expend significant cash resources to fund its operations until the balance of the purchase price is paid. Accordingly, a significant portion of the sales price of a System may not be recognized until a fiscal quarter subsequent to the fiscal quarter in which the Company incurred marketing and sales expenses associated with that order.

**CHALLENGES OF GROWTH.** The Company intends to use a portion of the net proceeds of the European Offering to hire and retain sales and marketing, research and development and technical personnel to increase and support sales of Systems and to develop additional surgical applications for its orthopaedic and neurosurgical systems. The anticipated growth of the Company will likely result in new and increased responsibilities for management personnel and place significant strain upon the Company's management, operating and financial systems and resources. To accommodate such growth and compete effectively, the Company must continue to implement and improve its operational, financial, management and information systems, procedures and controls, and to expand, train, motivate and manage its personnel. There can be no assurance that the Company's personnel, systems, procedures and controls will be adequate to support the Company's future operations. Any failure to implement and improve the Company's operational, financial, management and information systems, procedures or controls, or to expand, train, motivate or manage employees, could materially and adversely affect the Company's business, financial condition and results of operations.

**DEPENDENCE ON PRINCIPAL PRODUCT.** For the near term, the Company expects to derive most of its revenues from sales of the ROBODOC System. Accordingly, the Company's potential future success and financial performance will depend almost entirely on its ability to successfully market its ROBODOC System. If the Company is unable to obtain the requisite regulatory approvals or to achieve commercial acceptance of its ROBODOC System, the Company's business, financial condition and results of operations will be materially and adversely affected. The Company has not obtained, and there can be no assurance that the Company will obtain, clearance or approval to market the ROBODOC System in the United States. See "Risk Factors -- Government Regulation."

**UNCERTAINTY OF MARKET ACCEPTANCE.** The Company's ability to successfully commercialize its Systems will require substantial marketing efforts and the expenditure of significant funds to inform potential customers, including hospitals and physicians, of its distinctive characteristics and the advantages of using the Systems instead of traditional surgical tools and procedures. Since the Systems employ innovative technology, rather than being an improvement of existing technology, and represents a substantial capital expenditure, the Company expects to encounter resistance to change, which it must overcome to successfully market its products. Failure of the Systems to achieve significant market acceptance would materially and adversely affect the Company's business, financial condition and results of operations.

**COMPETITION.** The principal competition for the ROBODOC System is manual surgery performed by orthopaedic surgeons, using surgical power tools and manual devices. The providers of these instruments are the major orthopaedic companies, which include Howmedica, Inc. (a subsidiary of Pfizer, Inc.), located in New York; Zimmer, Inc. (a subsidiary of Bristol-Myers Squibb Company), located in Indiana; Johnson & Johnson Orthopaedics, Inc. (a subsidiary of Johnson & Johnson), located in New Jersey; DePuy, Inc. located in Indiana; Biomet, Inc., located in Indiana; and Osteonics, Inc. (a subsidiary of the Stryker Corporation), located in New Jersey. MAQUET, a manufacturer of operating tables located in Germany, has recently announced that it intends to market a device similar to ROBODOC System in mid 1998. The principal competition for the NeuroMate System are frame-based and frameless navigators, which are manually operated. Approximately twenty navigator models have been introduced, including those by Radionics, Sofamor-Danek and Ohio Medical Surgical products, all located in the United States; Elekta, located in Sweden; and Fischer Leibinger and Brain Lab, both located in Germany. In general, there are companies in the medical products industry capable of developing and marketing computer-controlled robotic systems for surgical applications, many of whom have significantly greater financial, technical, manufacturing, marketing and distribution resources than the Company, and have established reputations in the medical device industry. Furthermore, there can be no assurance that IBM or the University of California, which developed the technology embodied in the ROBODOC System and hold patents relating thereto, will not enter the market or license the technology to other companies.

There can be no assurance that future competition will not have a material adverse effect on the Company's business. The cost of the Systems represents a significant capital expenditure for a customer and accordingly may discourage purchases by certain customers.

AVAILABLE CLINICAL DATA; RISK VERSUS BENEFIT ISSUES. The Company has conducted a randomized clinical trial for the ROBODOC System in the United States at three centers. Of the 120 patients enrolled in the U.S. clinical study, 71 hips received treatment with the ROBODOC System and 65 hips in a control group received conventional THR surgery. In addition, at least 1,400 patients have received treatment with the ROBODOC System in Europe, although not as a part of the formal U.S. clinical study and without comparison to randomized control patients.

In order to obtain FDA clearance or approval, the Company will be required to demonstrate that the ROBODOC System is safe and effective. This can include a requirement to show a clinical benefit to patients. The Company believes that a reduced incidence of intraoperative fractures with the ROBODOC System compared to conventional THR surgery would offer an important benefit. The number of patients enrolled in the U.S. clinical study is less than the 300 patients (150 ROBODOC System; 150 control group) initially requested to be studied by the Company in its Investigational Device Exemption ("IDE") application to the FDA. Nonetheless, there have been at least 1,500 primary THR surgeries performed with the ROBODOC System in the combined U.S. clinical trial and the European study without a single intraoperative fracture. Since the observed fracture rate in the control group in the U.S. clinical trial was lower than anticipated, the data from this study are not sufficient to establish a statistically significant reduction in intraoperative fractures compared to the control group. Nevertheless, the data from both the U.S. trial and the European study suggest that the ROBODOC System reduces intraoperative fractures when compared to the fracture rate of approximately 6 to 24 percent for conventional THR surgery reported in the scientific and medical literature. There can be no assurance, however, that the FDA will agree that the ROBODOC System offers a clinically significant reduction in intraoperative fractures, in the absence of a controlled trial demonstrating such a reduction.

The FDA has advised the Company that the agency believes long-term functional and pain assessments are the primary endpoints for evaluating the safety and effectiveness of the ROBODOC System. A preliminary review by the Company of the functional and pain assessment data from the U.S. clinical trial shows equivalence between the ROBODOC System and conventional THR surgery. The Company believes that achieving better implant fit and alignment in the femoral cavity are significant factors in the success of cementless THR surgery, although the FDA has questioned whether fit is an appropriate endpoint and has not addressed alignment.

The Company's preliminary comparison completed in May 1997 of fit and alignment parameters from the 3 month radiographs showed that the ROBODOC System surgeries produced fit and alignment equivalent to conventional THR surgeries. Subsequently, the Company's outside radiologist and outside biostatistician have refined the analytical technique applied to the 3-month radiographic data in a manner that the Company believes more accurately reflects the implant manufacturers' design goals for implant cavity preparation. Based upon the preliminary results of this technique, the Company believes that the data will show that the ROBODOC System achieves better fit and alignment compared to conventional THR surgeries. The Company also will be reviewing long term fit and alignment. Although the Company believes that the refined technique produces a more appropriate comparison, there can be no assurance that the FDA will accept the Company's methodology for measuring fit and alignment, that the data, once fully reviewed and analyzed, will demonstrate that the ROBODOC System achieves better implant fit and alignment, or that the FDA will agree that better fit and alignment are significant surgical endpoints. In addition, there can be no assurance that the FDA will agree that the greater surgery time and blood loss associated with the ROBODOC System does not pose a significant safety concern or create an unfavorable risk/benefit ratio. Further, no assurance can be given that the FDA will not require the Company to obtain additional clinical data from a randomized, controlled trial to resolve any concern about the risk/benefit ratio offered by the ROBODOC System. If the Company were required to obtain such additional data, the FDA review process could be prolonged by several years.

In prior communications with the Company, the FDA indicated a strong "preference" for two year post-operative data from patients participating in the U.S. clinical trial, although in a late 1996 meeting the FDA indicated that it may accept a PMA application for filing with only two year post-operative data on some patients and permit the Company to submit the additional post-operative data while the PMA application is under review. However, there can be no assurance that the FDA will not require complete two-year post-operative data on all patients participating in the U.S. clinical trial before accepting a PMA application for filing. The last patient who has received surgery in the U.S. clinical trial will reach the two year post-operative mark in February 1998.

In February 1995, a law firm specializing in FDA regulatory matters examined an interim report of preliminary data and concluded that it was doubtful that the FDA would find that the device was safe and effective for its intended use, or provided a therapeutic benefit, sufficient to permit PMA approval, if the FDA were presented with the then existing preliminary data or future data qualitatively similar to the preliminary data. The Company believes that the additional data analyzed subsequent to the law firm's February 1995 report address many of the concerns identified in that report. These data and analyses include non-radiographic clinical follow-up data from the U.S. trial, preliminary analysis and review by an outside radiologist and an outside biostatistician of 3-month radiographic films from the U.S. trial, and data on additional patients from the European studies. The Company also is in the process of collecting 12-month and 24-month follow-up clinical (including radiological) data for patients in the U.S. clinical trial and obtaining analyses and review from the outside consultants, which process is expected to be completed by the end of 1997 or early 1998. There can be no assurance that the data, once fully analyzed and reviewed, will demonstrate that the ROBODOC System is safe and effective for its intended use, provides a therapeutic benefit, or has an acceptable risk/benefit ratio in light of increased surgery time and intraoperative blood loss. In addition, the Company's Director of Regulatory Affairs and Quality Assurance resigned in September 1996 and subsequently has asserted that one of the reasons for his resignation was his concern, similar to that expressed in the February 1995 law firm report, about the adequacy of the Company's clinical data to support product approval. See "Risk Factors -- U.S. Regulation -- FDA Review Process for ROBODOC System."

If the FDA concludes that the existing clinical data are insufficient to establish the safety and efficacy of the ROBODOC System, the FDA could require the Company to obtain additional clinical data from a randomized, controlled trial, which could significantly delay completion of the PMA review process, and which could accordingly have a material adverse effect on the Company's business, financial condition and results of operations.

#### GOVERNMENT REGULATION.

Summary. The Company's products are subject to continued and pervasive regulation by the FDA and foreign and state regulatory authorities. In the United States, the Company must comply with food and drug laws and with regulations promulgated by the FDA. These laws and regulations require the Company's products to obtain various authorizations prior to being marketed in the United States, and there is no assurance the Company's products will receive these authorizations. The Company's manufacturing facilities and practices will also be subject to FDA regulations. In each foreign market, the Company's products may be subject to substantially different regulations. Failure to comply with U.S. or applicable foreign regulations could have a material adverse effect on the Company.

#### U.S. REGULATION.

General. Pursuant to the Federal Food, Drug, and Cosmetic Act, as amended, and regulations thereunder (collectively, the "FDC Act"), the FDA regulates the clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices in the United States. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals, and criminal prosecution. The FDA also has the authority to request recall, repair, replacement or refund of the cost of any device manufactured or distributed by the Company. Failure to comply with regulatory requirements, including any

future changes to such requirements, could have a material adverse effect on the Company's business, financial condition and results of operation.

FDA Review Process for ROBODOC System. Before a new device can be introduced into the U.S. market, the manufacturer must obtain FDA permission to market through either the 510(k) pre-market notification process for medical devices which are substantially similar to other approved medical devices or the costlier, lengthier and less certain pre-market approval ("PMA") application process. The Company previously announced its intention to submit a PMA in late 1997 for approval to market the ROBODOC System in the United States. The Company currently is exploring a regulatory strategy that may allow the Company to pursue FDA clearance of the ROBODOC System through a 510(k) submission in lieu of a PMA application, which would be a less onerous and lengthy regulatory path if such an approach were acceptable to the FDA. The Company is currently gathering and evaluating clinical and radiographic data from the U.S. clinical trial and European studies. Therefore, the submission of a 510(k) notification or PMA application will be delayed beyond the projected late 1997 date. Pursuant to this strategy, the Company intends to request that the FDA review the Company's clinical and radiographic data in connection with a pre-filing meeting with FDA representatives. The Company intends to provide the data to the FDA by the end of 1997 or in early 1998. The purpose of the pre-filing meeting would be to seek feedback from the FDA about whether a 510(k) clearance pathway is a viable alternative to a PMA application for the ROBODOC System and to provide additional data to the FDA, including information in support of the Company's belief that implant fit and alignment are significant clinical endpoints. Although the FDA previously indicated to the Company that the ROBODOC System was more likely to require PMA approval rather than 510(k) clearance, the Company believes that the recent 510(k) clearance of a potential predicate device may offer a new basis for seeking 510(k) clearance for the ROBODOC System based, in part, upon a claim that the ROBODOC System is substantially equivalent to this predicate device. There can be no assurance that the FDA will agree to a pre-filing meeting with the Company or will provide the Company with feedback as to whether a 510(k) submission is a possible alternative to a PMA application for the ROBODOC System or will agree with the Company's assessment of the appropriate endpoints.

Unless the FDA rules out the 510(k) clearance path, the Company currently intends to submit a 510(k) notification to the FDA sometime during the first quarter of 1998. On the other hand, if the FDA indicates that a PMA application will be required, the filing of a PMA application by the Company could be delayed until the latter part of 1998 or later. These submission time frames could be substantially extended if the FDA indicates that the existing clinical data is insufficient to support clearance or approval or that additional clinical data will be necessary in order to submit a 510(k) notification or PMA application for the ROBODOC System. The Company's submission of a PMA application also could be delayed if the Company invests substantial time pursuing 510(k) clearance but is ultimately unsuccessful. There can be no assurance that the FDA will grant 510(k) clearance or PMA approval to the ROBODOC System on a timely basis, or at all, or that such clearance or approval will not include unfavorable limitations or restrictions. See "Risk Factors -- Available Clinical Data; Risk Versus Benefit Issues."

New surgical applications for the ROBODOC System generally will require FDA clearance or approval of a new 510(k) submission or a PMA supplement or, possibly, a new PMA application. The Company is also likely to require additional FDA approvals, supported by additional clinical data, before incorporating new imaging modalities such as ultrasound and MRI or other different technologies in the ROBODOC System.

No Assurance of Approvals; Subsequent Review of Approvals, Etc. There can be no assurance that any of the Company's current or future products will obtain required FDA approvals on a timely basis, or at all, or that the Company will have the necessary resources to obtain such approvals. If any of the Company's products are not approved for use in the United States, the Company will be limited to marketing them in foreign countries. Furthermore, approvals that have been or may be granted are subject to continual review, and later discovery of previously unknown problems can result in product labeling restrictions or withdrawal of the product from the market.

Adverse Effect of Delays or Loss of Approvals. Delays in the receipt of, or failure to receive, FDA approvals or clearances, or the loss of any previously received approvals or clearances, or limitations on

intended use imposed as a condition of such approvals or clearances, would have a material adverse effect on the business, financial condition and results of operations of the Company.

**Requirement to Follow Good Manufacturing Practices.** Assuming the Company obtains the necessary FDA approvals and clearances for its products, in order to maintain such approvals and clearances the Company will be required, among other things, to register its establishment and list its devices with the FDA and with certain state agencies, maintain extensive records, report any adverse experiences on the use of its products and submit to periodic inspections by the FDA and certain state agencies. The FDC Act also requires devices to be manufactured in accordance with the Quality System Regulation ("QSR"), which sets forth good manufacturing practices ("GMP") requirements with respect to manufacturing and quality assurance activities. The QSR revises the previous GMP regulation and imposes certain enhanced requirements that are likely to increase the cost of compliance, including design controls.

**Modifications to Cleared Devices.** The Company has made what it believes are nonsignificant modifications to the ORTHODOC and the NeuroMate System which the Company believes do not require the submission of new 510(k) notices. There can be no assurance, however, that the FDA would agree with any of the Company's determinations not to submit a new 510(k) notice for any of these changes or would not require the Company to submit a new 510(k) notice for any of the changes made to the device. If the FDA requires the Company to submit a new 510(k) notice for any device modification, the Company may be prohibited from marketing the modified device until the 510(k) notice is cleared by the FDA.

**FOREIGN REGULATION.** The introduction of the Company's products in foreign markets has subjected and will continue to subject the Company to foreign regulatory clearances, which may be unpredictable and uncertain, and which may impose substantial additional costs and burdens. The ROBODOC and NeuroMate Systems satisfy the appropriate international electromedical safety standards and comply with the requirements of the Electromagnetic Compatibility Directive, thus allowing the Company to apply the CE Mark under the European Directives and to distribute the ROBODOC and NeuroMate Systems throughout the European Union. Outside the European Union, international sales of medical devices are subject to the regulatory requirements of each country. The regulatory review process varies from country to country. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on devices. No assurance can be given that any additional necessary approvals or clearances for the Company's products will be granted on a timely basis, or at all.

#### UNCERTAINTY REGARDING PATENTS AND PROTECTION OF PROPRIETARY TECHNOLOGY.

**Summary.** Certain technology underlying the Company's products is the subject of one United States patent issued to IBM, which IBM has agreed not to enforce against the manufacture and sale of the Company's products, and five patent applications by the Company, the outcome of which applications is uncertain. Third party claims to the technology used in the Company's products could, if valid, require the Company to obtain licenses to the technology; those licenses may not be available on acceptable terms. The technology used in the Company's products could be (a) disclosed by Company employees despite their confidentiality obligations to the Company or (b) independently developed or otherwise acquired by potential competitors.

**General.** The Company's ability to compete successfully may depend, in part, on its ability to obtain and protect patents, protect trade secrets and operate without infringing the proprietary rights of others. The Company's policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications relating to its technology, inventions and improvements that are important to the development of its business. The Company has filed five patent applications, and is preparing for filing additional patent applications covering various aspects of its technology. In addition, IBM has agreed not to assert infringement claims against the Company with respect to an IBM patent relating to robotic medical technology, to the extent such technology is used in the Company's products. Significant portions of the ROBODOC System and ORTHODOC software are protected by copyrights. IBM has granted the Company a royalty-free license for the underlying software code for the ROBODOC System.



There can be no assurance that the Company's pending or future patent applications will mature into issued patents, or that the Company will continue to develop its own patentable technologies. Further, there can be no assurance that any patents that may be issued in the future will effectively protect the Company's technology or provide a competitive advantage for the Company's products or will not be challenged, invalidated, or circumvented in the future. In addition, there can be no assurance that competitors, many of which have substantially more resources than the Company and have made substantial investments in competing technologies, will not obtain patents that will prevent, limit or interfere with the Company's ability to make, use or sell its products either in the United States or internationally.

**Secrecy of Patent Applications Until Patents Issued.** Patent applications in the United States are maintained in secrecy until patents' issue, and patent applications in foreign countries are maintained in secrecy for a period after filing. Publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries and the filing of related patent applications. Patents issued and patent applications filed relating to medical devices are numerous and there can be no assurance that current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights relating to products or processes used or proposed to be used by the Company.

**Lack of Infringement Study.** The Company's patent counsel has not undertaken any infringement study to determine if the Company's products and pending patent applications infringe on other existing patents due to the Company's belief that an infringement study would not be cost-effective, nor offer sufficient protection against potential infringement claims, if and when made. The medical device industry has been characterized by substantial competition and litigation regarding patent and other proprietary rights. The Company intends to vigorously protect and defend its patents and other proprietary rights relating to its proprietary technology. Litigation alleging infringement claims against the Company (with or without merit), or instituted by the Company to enforce patents and to protect trade secrets or know-how owned by the Company or to determine the enforceability, scope and validity of the proprietary rights of others, is costly and time consuming. If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceedings, the Company could be prevented from practicing the subject matter claimed in such patents, or could be required to obtain licenses from the patent owners of each patent, or to redesign its products or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be available on terms acceptable to the Company or that the Company would be successful in any attempt to redesign its products or processes to avoid infringement. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from manufacturing and selling its products, which would have a material adverse effect on the Company's business, financial condition and results of operations.

**Possibility of Disclosure or Discovery of Proprietary Information.** Although the Company requires each of its employees, consultants, and advisors to execute confidentiality and assignment of inventions and proprietary information agreements in connection with their employment, consulting or advisory relationships with the Company, there can be no assurance that these agreements will provide effective protection for the Company's proprietary information in the event of unauthorized use or disclosure of such information. Furthermore, no assurance can be given that competitors will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's proprietary technology, or that the Company can meaningfully protect its rights in unpatented proprietary technology.

**LIMITED PRODUCTION EXPERIENCE.** The Company's success will depend in part on its ability to assemble its products in a timely, cost-effective manner and in compliance with GMP, and manufacturing requirements of other countries, including the International Standards Organization ("ISO") 9000 standards and other regulatory requirements. The assembly of the Company's products is a complex operation involving a number of separate processes and components. The Company's production activities to date have consisted primarily of assembling limited quantities of systems for use in clinical trials and a limited number of systems for commercial sale. The Company does not have experience in assembling its products in the commercial quantities that might be required. Furthermore, as a condition to receipt of PMA approval, the Company's facilities, procedures and practices will be subject to pre-approval and ongoing GMP inspections by FDA.

Manufacturers often encounter difficulties in scaling up manufacturing of new products, including problems involving product yields, quality control and assurance, component and service availability, adequacy of control policies and procedures, lack of qualified personnel, compliance with FDA regulations, and the need for further FDA approval of new manufacturing processes and facilities. There can be no assurance that production yields, costs or quality will not be adversely affected as the Company seeks to increase production, and any such adverse effect could have a material adverse effect on the Company's business, financial condition and results of operations.

**DEPENDENCE ON SUPPLIER FOR ROBOT.** Although the Company has multiple sources for most of the components, parts and assemblies used in the ROBODOC and NeuroMate Systems, the Company is dependent on Sankyo Seiki of Japan for the ROBODOC System robot and Audemars-Piguet of Switzerland for the supply of the customized NeuroMate robot. The robot for either the ROBODOC System or the NeuroMate System can be obtained from other suppliers with appropriate modifications and engineering effort. If the Company were no longer able to obtain the robot from its supplier, there can be no assurance that the delays resulting from the required modifications or engineering effort to adapt alternative components would not have a material adverse effect on the Company's business, financial condition and results of operations.

**RELIANCE ON FOREIGN SALES.** From inception through September 30, 1997, substantially all of the Company's sales (other than clinical sales in the United States pursuant to an exemption in the rules and regulations of the FDA for investigational devices) have been to customers in Germany, Austria, France and Japan. The Company believes that until such time, if ever, as it receives approval from the FDA to market the ROBODOC System in the United States, substantially all of its sales for the ROBODOC System will be derived from customers in foreign markets. Foreign sales are subject to certain risks, including economic or political instability, shipping delays, fluctuations in foreign currency exchange rates, changes in regulatory requirements, custom duties and export quotas and other trade restrictions, any of which could have a material adverse effect on the Company's business. To date, payment for substantially all ROBODOC Systems in Europe has been fixed in U.S. Dollars. However, there can be no assurance that in the future the customers will be willing to make payment to the Company for its products in U.S. Dollars. If the U.S. Dollar strengthens substantially against the foreign currency of a country in which the Company sells its products, the cost of purchasing the Company's products in U.S. Dollars would increase and may inhibit purchases of the Company's products by customers in that country. The Company is unable to predict the nature of future changes in foreign markets or the effect, if any, they might have on the Company.

**UNCERTAINTY CONCERNING THIRD PARTY REIMBURSEMENT.** The Company expects that its ability to successfully commercialize its products will depend significantly on the availability of reimbursement for surgical procedures using the Company's products from third-party payors such as governmental programs, private insurance and private health plans. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. Notwithstanding FDA approval, if granted, third-party payors may deny reimbursement if the payor determines that a therapeutic medical device is unnecessary, inappropriate, not cost-effective or experimental or is used for a nonapproved indication. Although the Company is not aware of any potential customer that has declined to purchase the ROBODOC System based upon third party reimbursement policies, cost control measures adopted by third-party payors may have a significant effect on surgeries performed with the ROBODOC System or as to the levels of reimbursement. There also can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third-party payors will not otherwise adversely affect the demand for the Company's products or its ability to sell its products on a profitable basis. Fundamental reforms in the healthcare industry in the United States and Europe that could affect the availability of third-party reimbursement continue to be proposed, and the Company cannot predict the timing or effect of any such proposal. If third-party payor coverage or reimbursement is unavailable or inadequate, the Company's business, financial condition and results of operation could be materially and adversely affected.

**DEPENDENCE ON KEY PERSONNEL.** The Company's business and marketing plan was formulated by, and is to be implemented under the direction of, Dr. Ramesh C. Trivedi, the Chief Executive Officer and President of the Company. Dr. Trivedi is employed by the Company pursuant to an employment agreement terminable

by the Company or Dr. Trivedi at any time. The Company has obtained key-man insurance on the life of Dr. Trivedi in the amount of \$1,000,000. The Company's growth and future success also will depend in large part on the continued contributions of its key technical and senior management personnel, as well as its ability to attract, motivate and retain highly qualified personnel generally and, in particular, trained and experienced professionals capable of developing, selling and installing the Systems and training surgeons in their use. Competition for such personnel is intense, and there can be no assurance that the Company will be successful in hiring, motivating or retaining such qualified personnel. None of the Company's executive or key technical personnel, other than Dr. Trivedi, is employed by the Company pursuant to an employment agreement with the Company. The loss of the services of Dr. Trivedi or other senior management or key technical personnel, or the inability to hire or retain qualified personnel, could have a material adverse effect on the Company's business, financial condition and results of operations.

**CONTROL OF THE COMPANY; OWNERSHIP OF SHARES BY CURRENT MANAGEMENT AND PRINCIPAL SECURITYHOLDERS.** The executive officers, directors and other significant securityholders of the Company own or have rights to acquire 4,158,673 shares of Common Stock (or approximately 37% of the shares of Common Stock on a fully diluted basis). Although these securityholders may or may not agree on any particular matter that is the subject of a vote of the stockholders, these securityholders may be effectively able to control the outcome of any issues which may be subject to a vote of securityholders, including the election of directors, proposals to increase the authorized capital stock, or the approval of mergers, acquisitions, or the sale of all or substantially all of the Company's assets.

**NEED FOR ADDITIONAL FINANCING.** Although the Company anticipates that the net proceeds of the European Offering, together with cash flow from operations, will be sufficient to finance its operations through 1999, there can be no assurance that the Company will not require additional financing at an earlier date. This will depend upon the Company's ability to generate sufficient sales of its products, and the timing of required expenditures. If the Company is required to obtain financing in the future, there can be no assurance that such financing will be available on terms acceptable to the Company, if at all.

**PRODUCT LIABILITY.** The manufacture and sale of medical products exposes the Company to the risk of significant damages from product liability claims. The Company maintains product liability insurance against product liability claims in the amount of \$5 million per occurrence and \$5 million in aggregate. In addition, in connection with the sale of ROBODOC Systems, the Company enters into indemnification agreements with its customers pursuant to which the customers indemnify the Company against any claims against it arising from improper use of the ROBODOC System. There can be no assurance, however, that the coverage limits of the Company's insurance coverage, that such insurance can be maintained at acceptable costs, or that customers will be able to satisfy indemnification claims. Although the Company has not experienced any product liability claims to date, a successful claim brought against the Company in excess of its insurance coverage could have a materially adverse effect on the Company's business, financial condition, and results of operations.

**LIMITATION ON DIRECTOR LIABILITY.** The Company's certificate of incorporation provides that a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, with certain exceptions under Delaware law. This may discourage stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on behalf of the Company against a director. In addition, the Company's By-laws provide for mandatory indemnification of directors and officers.

**ABSENCE OF DIVIDENDS.** Since inception, the Company has not paid any dividends on its Common Stock and it does not anticipate paying such dividends in the foreseeable future. The Company intends to retain earnings, if any, to finance its operations.

**POSSIBLE VOLATILITY OF MARKET PRICE FOR THE COMMON STOCK.** Since the completion of the Company's initial public offering in November 1996, the market price of the Common Stock has fluctuated significantly. The Company believes that factors such as announcement of developments related to the Company's business, announcements of technological innovations or new products by the Company or its competitors, sales of the Company's Common Stock in the public market, and shortfalls or changes in the Company's financial results

from analysts' expectations could cause the price of the Common Stock to fluctuate substantially. The Company's operating results and various factors affecting the medical device industry generally also may significantly impact the market price of the Company's securities. In addition, the stock market generally, and the securities of technology companies in particular, have experienced a high level of price and volume volatility, and market prices for the securities of many companies have experienced wide price fluctuations not necessarily related to the operating performance of such companies. There can be no assurance that the market price of the Common Stock will not experience significant fluctuations or decline below the public offering price.

**SHARES ELIGIBLE FOR FUTURE SALE.** No assurance can be given as to the effect, if any, that future sales of Common Stock, or the availability of shares of Common Stock for future sales, will have on the market price of the Common Stock from time to time. Sales of substantial amounts of Common Stock (including shares issued upon the exercise of warrants or stock options), or the possibility of such sales, could adversely affect the market price of the Common Stock and also impair the Company's ability to raise capital through an offering of its equity securities in the future. The Company has 5,490,811 shares of Common Stock outstanding, of which only 3,660,570 shares of Common Stock are transferable without restriction under the Securities Act of 1933 (the "Securities Act"). The remaining 1,830,238 shares, issued in private transactions, are "restricted securities" (as that term is defined in Rule 144 promulgated under the Securities Act) which may be publicly sold only if registered under the Securities Act or if sold in accordance with an applicable exemption from registration, such as Rule 144. In general, under Rule 144 as currently in effect, subject to the satisfaction of certain other conditions, a person, including an affiliate of the Company, who has beneficially owned restricted securities for at least one year, is entitled to sell (together with any person with whom such individual is required to aggregate sales), within any three-month period, a number of shares that does not exceed the greater of 1% of the total number of outstanding shares of the same class or, if the Common Stock is quoted on Nasdaq or a national securities exchange, the average weekly trading volume during the four calendar weeks preceding the sale. A person who has not been an affiliate of the Company for at least three months and who has beneficially owned restricted securities for at least two years is entitled to sell such restricted securities under Rule 144 without regard to any of the limitations described above. Officers, directors and the other existing securityholders of the Company, owning or having rights to acquire in the aggregate 5,129,759 shares of Common Stock constituting restricted securities, have agreed not to sell or otherwise dispose of any shares of Common Stock prior to May 21, 1998 ("Lock-Up Agreements"), without the prior written consent of Rickel & Associates, Inc. ("Rickel"), managing underwriter of the Company's initial public offering. Rickel has agreed with the Company and CA IB that it will not consent to the sale of such shares prior to that date. Following expiration of the term of the Lock-Up Agreements, 1,828,778 shares of Common Stock will become eligible for resale pursuant to Rule 144 commencing in the second quarter of 1998, subject to the volume limitations and compliance with the other provisions of Rule 144. In addition, securityholders of the Company owning or having rights to acquire in the aggregate 4,030,649 shares of Common Stock granted certain registration rights with respect to those shares have agreed that they will not exercise such registration rights prior to May 21, 1998. The Company granted Rickel demand and piggyback registration rights with respect to the shares of Common Stock and warrants issuable upon exercise of the underwriters' warrants issued in connection with the Company's initial public offering and piggyback registration rights (fully subordinated to the registration rights of the other holders of the Company's securities) with respect to 25,000 shares of Common Stock purchasable upon exercise of certain other warrants. In addition, the Company has granted the holders of warrants to purchase 150,000 shares of Common Stock issued to CA IB and Value Management & Research GmbH ("VMR") in connection with the European Offering demand and piggyback registration rights with respect to the shares of Common Stock issuable upon exercise thereof.

**EFFECT OF ISSUANCE OF COMMON STOCK UPON EXERCISE OF WARRANTS AND OPTIONS; POSSIBLE ISSUANCE OF ADDITIONAL OPTIONS.** The Company has an aggregate of 4,228,069 shares of Common Stock authorized but unissued and not reserved for specific purposes and an additional 5,281,120 shares of Common Stock unissued but reserved for issuance upon exercise of (i) options granted pursuant the Company's stock option plans, and (ii) outstanding warrants. All of such shares may be issued without any action or approval by the Company's stockholders. Although except for issuances upon exercise of outstanding options or warrants there are no

present plans, agreements, commitments or undertakings with respect to the issuance of additional shares of Common Stock or securities convertible into any such shares by the Company, any shares issued would further dilute the percentage ownership of the Company held by the public stockholders. The Company has agreed with Rickel that it will not issue any securities or rights thereto, other than shares of Common Stock issuable upon exercise of the warrants issued in the Company's initial public offering (the "Public Warrants") and options granted pursuant to the Company's stock option plans, without its consent until November 21, 1999. Rickel, which ceased operations as a registered broker dealer on September 19, 1997, consented to the issuance of the Shares in connection with the Company's acquisition of IMMI and the securities issued in the European Offering. The Company also has agreed with CA IB that, except for shares of Common Stock issuable upon exercise of the Public Warrants and outstanding options granted pursuant to the Company's existing stock option plans, until May 20, 1998, it will not issue or sell, offer or contract to issue or sell, grant any option for issuance or sale of, or otherwise dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into, exchangeable for, or representing the right to receive Common Stock without, in each case, the prior written consent of CA IB, which consent will not be unreasonably withheld.

The exercise of warrants or options and the sale of the underlying shares of Common Stock (or even the potential of such exercise or sale) may have a depressive effect on the market price of the Company's securities. Moreover, the terms upon which the Company will be able to obtain additional equity capital may be adversely affected since the holders of outstanding warrants and options can be expected to exercise them, to the extent they are able, at a time when the Company would, in all likelihood, be able to obtain any needed capital on terms more favorable to the Company than those provided in the warrants and options.

**POSSIBLE ADVERSE EFFECT OF ISSUANCE OF PREFERRED STOCK.** The Company's certificate of incorporation authorizes the issuance of 1,000,000 shares of "blank check" preferred stock, with designations, rights and preferences determined from time to time by the Company's Board of Directors. Accordingly, the Company's Board of Directors is empowered, without further stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of the Common Stock. In the event of issuance, the preferred stock could be used, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company, since the terms of the preferred stock that might be issued could effectively restrict the Company's ability to consummate a merger, reorganization, sale of all or substantially all of its assets, liquidation or other extraordinary corporate transaction without the approval of the holders of the preferred stock. The Company has agreed with CA IB that, except for shares of Common Stock issuable upon exercise of the Public Warrants and outstanding options granted pursuant to the Company's existing stock option plans, until May 20, 1998, it will not issue or sell, offer or contract to issue or sell, grant any option for issuance or sale of, or otherwise dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into, exchangeable for, or representing the right to receive Common Stock without, in each case, the prior written consent of CA IB, which shall not be unreasonably withheld. However, there can be no assurance that preferred stock will not be issued at some time in the future. The Company has agreed with Rickel that it will not issue any securities or rights thereto, other than shares of Common Stock issuable upon exercise of the Public Warrants and options granted pursuant to the Company's stock option plans, without its consent until November 21, 1998. Rickel consented to the issuance of the Shares in connection with the Company's acquisition of IMMI and the securities issued in the European Offering.

In addition, the Company's Restated Certificate of Incorporation, as amended, authorizes the issuance of up to 5,750,000 shares of Series D Preferred Stock. On October 29, 1997, the Company delivered to CA IB an agreement not to issue any shares of the Series D Preferred Stock, or any options, warrants or other rights to subscribe for or purchase Series D Preferred Stock or any other securities convertible into, exercisable or exchangeable for, shares of the Series D Preferred Stock without the consent of CA IB. In addition, the Company's management has undertaken to cause the Board of Directors to present a resolution at the next annual meeting of the Company's stockholders to amend the Company's Restated Certificate of Incorporation to eliminate the Series D Preferred Stock. However, there can be no assurance that such resolution will be presented by the Company's Board of Directors, or, if presented, adopted by the Company's stockholders.

ANTITAKEOVER PROVISIONS OF DELAWARE BUSINESS COMBINATION STATUTE. The Company is subject to Section 203 of the Delaware General Corporation Law ("DGCL"), which limits transactions between a publicly held company and "interested stockholders" (generally, those stockholders who, together with their affiliates and associates, own 15% or more of a company's outstanding capital stock). This provision of the DGCL also may have the effect of deterring certain potential acquisitions of the Company.

RISKS ASSOCIATED WITH FORWARD-LOOKING STATEMENTS INCLUDED IN THIS PROSPECTUS. This Prospectus contains certain forward-looking statements regarding, among other items, the Company's expansion strategy. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the forward-looking statements included in this Prospectus will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved.

## SELLING STOCKHOLDERS

The table below sets forth, with respect to each Selling Stockholder, based upon information available to the Company as of December 1, 1997, the number of shares of Common Stock beneficially owned, the percentage ownership of Common Stock beneficially owned before the Offering, the number of shares of Common Stock to be sold, and the number of outstanding shares of Common Stock beneficially owned after the sale of the shares of Common Stock offered hereby. None of the Selling Stockholders has been an officer, director or affiliate of the Company during the preceding three years. Each of the Selling Stockholders acquired the shares of Common Stock offered hereby in exchange for securities of IMMI in connection with the acquisition of IMMI by the Company on September 5, 1997. Although there can be no assurance that the Selling Stockholders will sell any or all of the shares of Common Stock offered hereby, the following table assumes that each of the Selling Stockholders will sell all of such shares of Common Stock.

NAME	AMOUNT AND NATURE BENEFICIAL OWNERSHIP(1)	PERCENTAGE OF COMMON STOCK BENEFICIALLY OWNED BEFORE OFFERING(2)	SHARES OF COMMON STOCK TO BE SOLD	SHARES OF COMMON STOCK OWNED AFTER OFFERING
Farideh Danel.....	80,643	1.47%	80,643	0
Francois Danel.....	63,155	1.15%	63,155	0
Gerard Hascoet.....	194,028	3.53%	194,028	0
Jerome Lebon.....	33,917	*	33,917	0
Jean-Luc Boulnois.....	28,717	*	28,717	0
Fernand Badano.....	5,431	*	5,431	0
Pierre Wuergler.....	27,003	*	27,003	0
Georges-Henri Meylan.....	11,845	*	11,845	0
Enzo Filipini.....	10,478	*	10,478	0
Pierre Angelo Botinelli...	10,478	*	10,478	0
Giulio Merlani.....	10,478	*	10,478	0
Serge Tschopp.....	10,478	*	10,478	0
Raymond Bornand.....	10,478	*	10,478	0
Jacques-Louis Audemars....	6,279	*	6,279	0
Mohamed Diab.....	2,619	*	2,619	0
Gemed SA.....	113,328	2.06%	113,328	0

\* Less than 1%

(1) Unless otherwise indicated, each person has sole investment and voting power with respect to the shares indicated, subject to community property laws, where applicable. For purposes of computing the percentage of outstanding shares held by each Selling Stockholder on December 1, 1997, any security which such person has the right to acquire within 60 days after such date, is deemed to be outstanding for the purpose of computing the percentage ownership for such person, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person.

(2) Based upon 5,490,811 shares of Common Stock issued and outstanding.

## PLAN OF DISTRIBUTION

The Selling Stockholders may sell the Shares from time to time directly to purchasers, or through broker-dealers who may receive compensation in the form of commissions or discounts from the Selling Stockholders or purchasers. Sales of the Shares may be effected by broker-dealers in ordinary brokerage transactions or block transactions on The Nasdaq SmallCap Market, the Pacific Exchange or EASDAQ, through sales to one or more dealers who may resell as principals, in privately negotiated transactions or otherwise, at the market price prevailing at the time of sale, a price related to such prevailing market price or at a negotiated price. Usual and customary or specifically negotiated brokerage fees may be paid by the Selling Stockholders in connection therewith. To the Company's knowledge, none of the Selling Stockholders have entered into any underwriting arrangements for the sale of the Shares.

Pursuant to the terms of a Stock Purchase Agreement dated as of September 5, 1997, the Selling Stockholders have agreed not to sell the Shares prior to March 5, 1999, except as follows: (i) from December 6, 1997 through March 5, 1998, an aggregate of 50,000 shares plus 1% of the total number of shares of Common Stock traded on Nasdaq during the preceding three month period; (ii) from March 6, 1998 through June 5, 1998, an aggregate of 75,000 shares plus 1% of the total number of shares of Common Stock traded on Nasdaq during the preceding three month period; (iii) from June 6, 1998 through September 5, 1998, an aggregate of 100,000 shares plus 1% of the total number of shares of Common Stock traded on Nasdaq during the preceding three month period; (iv) from September 6, 1998 through December 5, 1998, an aggregate of 100,000 shares plus 1% of the total number of shares of Common Stock traded on Nasdaq during the preceding three month period; and (v) from December 6, 1998 through March 5, 1999, an aggregate of 100,000 shares plus 1% of the total number of shares of Common Stock traded on Nasdaq during the preceding three month period. Thereafter, the number of shares of Common Stock which may be sold during any three month period may not exceed the greater of 1% of the total number of outstanding shares of Common Stock or, if the Common Stock is quoted on Nasdaq or a national securities exchange, the average weekly trading volume during the four calendar weeks preceding the sale.

The Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act and any profits realized by them may be deemed to be underwriting commissions. Any broker-dealers that participate in the distribution of the Shares also may be deemed to be "underwriters", as defined in the Securities Act, and any commissions or discounts paid to them, or any profits realized by them upon the resale of any Shares purchased by them as principals, may be deemed to be underwriting commissions or discounts under the Securities Act. The sale of the Shares by the Selling Stockholders is subject to the prospectus delivery and other requirements of the Securities Act.

The Shares have been registered pursuant to registration rights granted to the Selling Stockholders. All costs, expenses and fees in connection with the registration of the Shares will be borne by the Company. The Selling Stockholders are responsible for the payment of brokerage commissions and discounts incurred in connection with the sale of the Shares. The Company has agreed to indemnify the Selling Stockholders against certain liabilities, including liabilities under the Securities Act.

Under the Exchange Act and the regulations thereunder, any person engaged in a distribution of the Common Stock offered by this Prospectus may not simultaneously engage in market-marking activities with respect to the Common Stock during the applicable "cooling off" period prescribed by Rule 101 of Regulation M prior to the commencement of such distribution. In addition, and without limiting the foregoing, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Rule 102 of Regulation M, which provisions may limit the timing of purchases and sales of Common Stock by the Selling Stockholders.

To the extent required, the Company will use its best efforts to file, during any period in which offers or sales of Shares are being made by or on behalf of the Selling Stockholders, one or more amendments or supplements to this Prospectus which describe any material information with respect to the plan of distribution not previously disclosed herein including the name or names of any underwriters, broker-dealers or agents, if any, the purchase price paid by any underwriter for Shares purchased from a Selling Stockholder, and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.



## LEGAL MATTERS

The validity of the Shares will be passed upon for the Company by Snow Becker Krauss P.C., 605 Third Avenue, New York, New York 10158-0125.

## EXPERTS

The consolidated financial statements of Integrated Surgical Systems, Inc. at December 31, 1996 and for each of the two years in the period ended December 31, 1996, appearing in the Company's Annual Report (Form 10-KSB) for the year ended December 31, 1996 and included in the Registration Statement (Form SB-2 No. 333-31481) and related Prospectus of Integrated Surgical Systems, Inc. dated November 14, 1997 have been audited by Ernst & Young LLP, independent auditors, as set forth in their reports thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Innovative Medical Machines International, S.A. at December 31, 1996 and for each of the two years in the period ended December 31, 1996, appearing in the Current Report (Form 8-K) dated September 5, 1997 as amended, of Integrated Surgical Systems, Inc., and included in the Registration Statement (Form SB-2 No. 333-31481) and the related Prospectus of Integrated Surgical Systems, Inc. dated November 14, 1997 have been audited by Ernst & Young Entrepreneurs Department D'Ernst & Young Audit, independent auditors, as set forth in their reports thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the estimated expenses which will be paid by the Registrant in connection with the issuance and distribution of the shares of Common Stock being registered hereby.

SEC Registration Fee.....	\$ 867.87
Printing expenses (other than stock certificates).....	7,500.00
Legal fees and expenses (other than blue sky).....	10,000.00
Accounting fees and expenses.....	5,000.00
Miscellaneous.....	1,632.13
	-----
Total.....	\$25,000.00
	=====

## ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Article VI of the Registrant's by-laws provides that a director or officer shall be indemnified against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement (provided such settlement is approved in advance by the Registrant) in connection with certain actions, suits or proceedings, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation -- a "derivative action") if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. A similar standard of care is applicable in the case of derivative actions, except that indemnification only extends to expenses (including attorneys' fees) incurred in connection with the defense or settlement of such an action, except that no person who has been adjudged to be liable to the Registrant shall be entitled to indemnification unless a court determines that despite such adjudication of liability but in view of all of the circumstances of the case, the person seeking indemnification is fairly and reasonably entitled to be indemnified for such expenses as the court deems proper.

Article 6.5 of the Registrant's by-laws further provides that directors and officers are entitled to be paid by the Registrant the expenses incurred in defending the proceedings specified above in advance of their final disposition, provided that such payment will only be made upon delivery to the Registrant by the indemnified party of an undertaking to repay all amounts so advanced if it is ultimately determined that the person receiving such payments is not entitled to be indemnified.

Article 6.4 of the Registrant's by-laws provides that a person indemnified under Article VI of the by-laws may contest any determination that a director, officer, employee or agent has not met the applicable standard of conduct set forth in the by-laws by petitioning a court of competent jurisdiction.

Article 6.6 of the Registrant's by-laws provides that the right to indemnification and the payment of expenses incurred in defending a proceeding in advance of its final disposition conferred in the Article will not be exclusive of any other right which any person may have or acquire under the by-laws, or any statute or agreement, or otherwise.

Finally, Article 6.7 of the Registrant's by-laws provides that the Registrant may maintain insurance, at its expense, to reimburse itself and directors and officers of the Registrant and of its direct and indirect subsidiaries against any expense, liability or loss, whether or not the Registrant would have the power to indemnify such persons against such expense, liability or loss under the provisions of Article VI of the by-laws. The Registrant maintains and has in effect such insurance.

Article 11 of the Registrant's certificate of incorporation eliminates the personal liability of the Registrant's directors to the Registrant or its stockholders for monetary damages for breach of their fiduciary

duties as a director to the fullest extent provided by Delaware law. Section 102(b)(7) of the DGCL provides for the elimination of such personal liability, except for liability (i) for any breach of the director's duty of loyalty to the Registrant or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived any improper personal benefit.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## ITEM 16. EXHIBITS

- 2.1 -- Stock Purchase Agreement dated as of September 5, 1997 between the Registrant and the holders of the outstanding capital stock of Innovative Medical Machines International, S.A.\*
- 2.2 -- Registration Rights Agreement dated September 5, 1997 by and among the Registrant and the holders of the outstanding capital stock of Innovative Medical Machines International, S.A.\*
- 5.1 -- Opinion of Snow Becker Krauss P.C.
- 23.1 -- Consent of Snow Becker Krauss P.C. (included in Exhibit 5.1 to this Registration Statement)
- 23.2 -- Consent of Ernst & Young LLP, independent auditors
- 23.3 -- Consent of Ernst & Young Entrepreneurs Department D'Ernst & Young Audit, Independent Auditor
- 24.1 -- Power of Attorney (included on the signature page of this Registration Statement)

\* Incorporated by reference to the Company's Registration Statement on Form SB-2 (Registration No. 333-31481) declared effective on November 14, 1997.

## ITEM 17. UNDERTAKINGS

## (a) RULE 415 OFFERING

The undersigned small business issuer hereby undertakes that it will:

(1) File, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) Include any prospectus required by section 10(a)(3) of the Securities Act.

(ii) Reflect in the prospectus any facts or events which, individually or in the aggregate, represent a fundamental change in the information set forth in the registrant statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) Include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) For determining any liability under the Securities Act, each such post-effective amendment shall be deemed a new registration statement relating to the securities offered therein, and the offering of such securities at that time to be the initial bona fide offering thereof.

(3) Remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

## (e) REQUEST FOR ACCELERATION OF EFFECTIVE DATE

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the small business issuer of the expenses incurred or paid by a director, officer, or controlling person of the small business issuer in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the small business issuer will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirement for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Sacramento in the State of California on December 10, 1997.

INTEGRATED SURGICAL SYSTEMS, INC.

By: /s/ RAMESH C. TRIVEDI

By: /s/ MARK W. WINN

-----  
 Ramesh C. Trivedi  
 Chief Executive Officer and President  
 (Principal Executive Officer)

-----  
 Mark W. Winn  
 Chief Financial Officer  
 (Principal Financial and Accounting  
 Officer)

KNOW ALL MEN BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Ramesh C. Trivedi and Mark Winn, acting singly, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to file the same and all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons on December 10, 1997, in the capacities indicated.

SIGNATURE	TITLE
-----	-----
/s/ RAMESH C. TRIVEDI	Chief Executive Officer, President, and
-----	Director (Principal Executive Officer)
Ramesh C. Trivedi	
/s/ MARK W. WINN	Chief Financial Officer (Principal Financial
-----	and Accounting Officer)
Mark W. Winn	
/s/ JAMES C. MCGRODDY	Chairman of the Board of Directors
-----	
James C. McGroddy	
/s/ JOHN N. KAPOOR	Director
-----	
John N. Kapoor	
/s/ PAUL A.H. PANKOW	Director
-----	
Paul A.H. Pankow	
/s/ GERALD D. KNUDSON	Director
-----	
Gerald D. Knudson	
	Director
-----	
Patrick G. Hayes	

## EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION	SEQUENTIALLY NUMBERED PAGE
5.1	-- Opinion of Snow Becker Krauss, P.C.	
23.1	-- Consent of Snow Becker Krauss, P.C. (included in Exhibit 5.1 to this Registration Statement)	
23.2	-- Consent of Ernst & Young LLP, independent auditors	
23.3	-- Consent of Ernst & Young Entrepreneurs Department D'Ernst & Young Audit, Independent Auditors	

SNOW BECKER KRAUSS P.C.  
Attorneys at Law  
605 Third Avenue  
New York, New York 10158

-----  
(212) 687-3860

December 10, 1997

Board of Directors  
Integrated Surgical Systems, Inc.  
829 West Stadium Lane  
Sacramento, California 95834

Ladies and Gentlemen:

You have requested our opinion, as counsel for Integrated Surgical Systems, Inc., a Delaware corporation (the "Company"), in connection with the registration statement (the "Registration Statement") on Form S-3, under the Securities Act of 1933 (the "Act"), filed by the Company with the Securities and Exchange Commission. The Registration Statement relates to an offering of 619,355 shares (the "Shares") of common stock, par value \$0.01 ("Common Stock"), of the Company by the selling stockholders named in the Registration Statement.

We have examined such records and documents and made such examinations of law as we have deemed relevant in connection with this opinion. Based upon the foregoing, it is our opinion that:

1. The Company has been duly organized, is validly existing and in good standing under the laws of the State of Delaware.
2. The Shares have been duly authorized and are legally issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Registration



Statement. In so doing, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Securities and Exchange Commission promulgated thereunder.

Very truly yours,

/s/ Snow Becker Krauss P.C.

SNOW BECKER KRAUSS P.C.

## CONSENT OF ERNST &amp; YOUNG LLP, INDEPENDENT AUDITORS

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3) and related Prospectus of Integrated Surgical Systems, Inc. for the registration of 619,355 shares of its common stock and to the incorporation by reference therein of our reports dated January 31, 1997, with respect to the consolidated financial statements of Integrated Surgical Systems, Inc. included in its Annual Report (Form 10-KSB) for the year ended December 31, 1996, and included in the Registration Statement (Form SB-2 No. 333-31481) and related Prospectus of Integrated Surgical Systems, Inc. dated November 14, 1997 filed with the Securities and Exchange Commission.

ERNST &amp; YOUNG LLP

Sacramento, California

December 10, 1997

## CONSENT OF ERNST &amp; YOUNG ENTREPRENEURS' DEPARTMENT

## D'ERNST &amp; YOUNG AUDIT, INDEPENDENT AUDITORS

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3) and related Prospectus of Integrated Surgical Systems, Inc. for the registration of 619,355 shares of its common stock and to the incorporation by reference therein of our reports dated September 10, 1997, with respect to the consolidated financial statements of Innovative Medical Machines International S.A. included in the Current Report (Form 8-K) dated September 5, 1997, as amended, of Integrated Surgical Systems, Inc., and included in the Registration Statement (Form SB-2 No. 333-31481) and related Prospectus of Integrated Surgical Systems, Inc. dated November 14, 1997 filed with the Securities and Exchange Commission.

ERNST &amp; YOUNG ENTREPRENEURS

DEPARTMENT D'ERNST & YOUNG  
AUDIT  
Marc Bonhomme  
Partner

Villeurbanne, France

December 10, 1997