Cambridge Consultants

Navigating Surgical Options:
The Future of Minimally Invasive Surgery

A Workshop Hosted by Cambridge Consultants

Cambridge Consultants recently hosted an event for key opinion leaders in the surgical industry. Discussions were seeded with the topic: 'Navigating Surgical Options: the future of minimally invasive surgery'. We asked the delegates to examine what the surgical landscape might look like a decade from now, focusing on the impact, enablers, and challenges of Minimally Invasive Surgery.

The delegates represented a wide spectrum of backgrounds including imaging and navigation, surgical robotics, regulatory affairs, laparoscopy and endoscopy. We are very grateful to our guests for their willingness to travel considerable distances in order to attend, and also for their readiness to share their insight and experience so freely. This report attempts to summarize the findings from the event, and offers a unique insight into the future of the industry as seen through the eyes of some of the sector's leading authorities.

We are also grateful to Don Ingber, Director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, for kick-starting the event with a thought provoking and stimulating presentation.

Participants

Amir Belson	Zipline
Järl Blijd	Philips Healthcare
Ken Bruener	BrainLAB, Inc.
Michael Clem	Ethicon Endo-Surgery
Robert Cunningham	RainDance Technologies
Diane Flynn	Volcano Corporation
Ken Horton	Covidien
Woojin Lee	Cambridge Endoscopic Devices, Inc.
Sally Maher	Smith & Nephew Endoscopy Division
Don Malackowski	Stryker Instruments
Dwight Meglan	HeartLander Surgical
Bryant Moore	Medtronic
Brett Naglreiter	Apollo Endosurgery
Dave Rosa	Intuitive Surgical
Brian Schmitz	MAKO Surgical Corp.
Christopher Thompson	Brigham and Women's Hospital
Ron von Jako	GE Healthcare
Andrew Wiles	NDI (Northern Digital, Inc.)
Guang-Zhong Yang	Imperial College London

Hosts

Tim Clay

Laura Clifton

Andrew Diston

David Gale

John Genova

Paula Gomes

Mark Manasas

Patrick Pordage

Rahul Sathe

Vital Signs

In 1991, the surgical community largely disapproved of the first successful laparoscopic radical prostatectomy, threatening to ban the surgeons from medical practice.

Nearly a decade later, in 2000, 98% of prostatectomies in the US were performed laparoscopically. In that same year, the da Vinci surgical robot received FDA clearance. By 2009, an estimated 90% of radical prostatectomies were performed via robotic surgery.

What will the coming decade hold for Minimally Invasive Surgery?

Despite challenging market conditions, the global MIS market remains strong, with a size of approximately $15 billion in 2009 and an estimated annual growth rate of 8% over the next 5 years. Investment in research and development continues to be restrained but, as economic conditions improve, venture funding is expected to experience a cyclical revival.

MIS products have historically been developed in isolation. More recently, fully integrated systems are emerging, enabling diagnosis, treatment, and follow-up all in the same day. Robotic-assisted surgery represents the fastest market segment growth, and strong performance is expected from image-guided surgery.

This report distills the key findings from discussions on the future of MIS, examining market dynamics, company growth, challenges in surgery, new technologies, and new markets for the coming decade.

Market Dynamics

Shifting Customer Power

Cost pressures and patient consumerism are causing an evolution in customer profiles. Surgeons and nurses were traditionally the gatekeepers in the purchasing decision for MIS instruments and equipment. This practice is rapidly changing, with hospital administrators, accountants, and patients now becoming stronger buying influences of MIS technology.

Hospital committees, typically comprised of surgeons and hospital administrators, often determine the purchase of new equipment and instruments. Surgeon influence on the purchasing decision is increasingly diminishing on these committees. In many purchasing scenarios, new technologies receive a thorough cost-effectiveness analysis, and are clinically assessed in tightly controlled case studies. This process, when run optimally, can streamline healthcare costs and also ensure new technologies are vetted appropriately. However, it is now a far more complex process to purchase instruments and equipment, as budgets are often subject to quarterly review cycles, and decisions can sometimes take months.

Hospitals now place greater focus on cost-benefit analysis and the business case for investing in new devices and procedures.

The disparity in economic sophistication of hospitals also creates a challenging sales environment for MIS companies to navigate. Some hospitals forecast clinical incidence with robust models and plan strategic growth accordingly. Six Sigma practices are employed to improve operating efficiency. Other hospitals are further behind on the learning curve, lacking the skills needed to economically assess new technology. The absence of this information often results in a significant barrier to purchasing new products. Here lies an opportunity for MIS companies to educate the less sophisticated hospitals in understanding the true economic value of their new products.

Patients are becoming strong buying influences for MIS technology, largely due to increasing patient access to information. Patients have the option to 'diagnose' themselves on Web-MD, and 'shop for docs' on Google. Patient choice is also empowering older patients receiving support from their internet-savvy children and grandchildren. As a result, physicians and surgeons must competitively demonstrate their value to patients.

Government policies now require more facts on procedures to be released to the public. Clinical Evaluation Reports disseminate valuable information for devices marketed in Europe. Companies also distribute information on diseases and devices to patients via websites and brochures, resembling the pharmaceutical industry's model of direct-to-consumer marketing. As a result, patients now request surgical treatments by brand or procedure.

The Rise of the Champion Integrator

Who will dominate the future sales channels? Not surprisingly, the workshop delegates had mixed views. Many agreed it will take a champion integrator to muster the resources, technical knowledge and supply chains. But the debate centered on which companies, or organizations, have the ability to execute.

With a rapidly evolving customer base, sales channels are changing, and companies that can best integrate technologies and services to own the sales channel will dominate their respective markets.

Imaging companies are often considered to have expertise in diagnostics and close relationships with hospitals, but have limited experience in therapy. Conversely, instrument manufacturers have depth and breadth of surgical experience, but traditionally lack knowledge in image processing and complex electronics and software. With changing customers and surgical procedures, both camps lack the depth to provide fully integrated solutions for changing customers and surgical procedures. The companies that can effectively navigate beyond their comfort zone will be best positioned to dominate the market, be it through organic growth, acquisition, or partnerships.

As a prime example of adapting to changing channels, several delegates cited the VScan® handheld ultrasound scanner, released in 2009. Named as one of the 50 best inventions of 2009 by Time Magazine, the scanner is slightly larger than a cell phone, and effectively takes ultrasound out of the hospital and into the field. The system is currently designed for use by medical personnel only. However, it is easy to imagine a time when expectant parents buy or rent such systems for home use.

Fall of the Hospital Conglomerate

The pendulum has swung from large centers of excellence at major hospitals to smaller specialized care centers. Historically, large hospitals developed into research machines, while mid-sized hospitals merged to form conglomerates, and smaller hospitals survived various economic cycles.

Large centers of excellence are not going away; institutions cultivate advanced research and fund infrastructure for capital-intensive procedures. Instead, with MIS a mainstay of surgical practice, physicians and surgeons are now establishing their own specialty practices by buying small hospitals, getting rid of unprofitable Emergency Rooms and focusing on high skill, high-throughput procedures.

Consequently, hospitals and private practices now compete aggressively at a local level. Many hospitals have bi-weekly newsletters, media departments, and interactive websites for patients. Some advertise their use of MIS technologies, ranging from robotic surgery to new imaging equipment, and seek to be early adopters of new procedures. Hospitals will continue to find MIS procedures an attractive offering for patient care, providing low risk to patients and high throughput for hospitals.

Patient Benefit, at What Cost?

Though healthcare cost has been a focus in both policy and society over the past year, the delegates unanimously agreed that patient benefit takes priority. Benefit is still the primary differentiator for products, but cost needs to be justified. New technologies need to enter the market as cost neutral, at a minimum, when compared to predicate devices or procedures. The delegates conceded that cost-effectiveness is difficult to measure, particularly over a long time period.

Not surprisingly, the goal of revenue generation conflicts with regulatory and policy pressures for long-term evidence of improved patient outcome. Increased financial and reimbursement pressures do not provide market incentive for long-term studies. As a result, MIS companies are shifting focus to markets that reward short-term evidence, where post-operative benefits are experienced quickly.

> *Regulatory pressures will drive MIS companies to plan clinical trials earlier, seek more clinical evidence, and leverage predicate data for effective outcomes comparisons.*

The delegates agreed that gathering long-term clinical evidence is desirable for patients and the industry. However, it is often difficult to obtain meaningful long-term data. Clinical outcomes can be quite subjective, or, even if quantifiable, may not necessarily correlate to actual healing. For knee cartilage plugs, as an example, post-operative and follow-up measurement standards are antiquated. One type of knee scoring system utilizes qualitative tests involving standing, walking, or bending the knees. This provides poor accuracy or resolution for differentiating outcomes. Unfortunately, long-term quantitative clinical data remains difficult to obtain in orthopedics – patients are simply unwilling to get cartilage biopsies five years after surgery.

Here technology can play a role. Embedded sensors could radically change outcomes by adding objectivity and flexible monitoring schedules. Sensors would act like an onboard computer in a car, providing information when interrogated wirelessly. The value of sensors will only be realized if data is actionable for the patient and if more supportive reimbursement coding exists for post-operative monitoring.

The focus on short-term evidence poses a challenge for long-term healthcare. If companies are not going to run clinical trials for long-term outcomes, perhaps surgical societies will take on the challenge. Various surgical societies such as NOSCAR, AMA, and SAGES already help raise awareness for long-term clinical and cost-effectiveness data. But societies are large organizations with many voices, and achieving consensus to organize a clinical trial is difficult and costly.

In the summer of 2009, the United States government established a $1.1 billion fund for Comparative Effectiveness Research, with the goal of supporting research that compares long-term clinical outcomes. This could allow societies, companies, and government agencies to collaborate on long-term outcomes for relevant therapies.

Policy Reform – Bracing for Impact

President Lyndon B. Johnson signed the Social Security Act of 1965, bringing to life Medicare and Medicaid and effectively catalyzing the medical device industry growth in the US. Will healthcare policy reform of 2010 do the same?

With US healthcare policy reform in its infancy at the time of the workshop, the delegates agreed it is too early to tell what impact, if any, new policies will have on the MIS industry. There were, however, some interesting points of discussion.

Regarding the 2.3% excise tax on medical devices, some delegates thought the impact would be small for companies in higher margin markets. Since the tax will not be implemented until 2013, the impact is beyond the financial horizon of quarterly earnings. Other delegates thought that, for lower margin markets, the tax could cause companies to reduce their R&D and marketing budgets.

The ‘worried well’ may be negatively affected by new policies. Patients needing surgeries involving sports medicine, ophthalmology, or plastic surgery are rapidly increasing in numbers. It may be more difficult to justify reimbursement for such procedures to insurance companies. This may create demand for a tiered payment system; necessary and emergency procedures will be reimbursed, while patients pay out of their pocket for early intervention, prevention, or enhancement procedures.

Managing Growth

A Rebirth for Funding

Champion integrators and distributors are expected to dominate markets, but will still require innovative products to maintain competitive advantage.

Large medical device companies previously invested heavily in innovation and organic growth. However, large firms continue to face pressures from stock price valuation and earnings reports, further amplified in financially uncertain markets. This distracts effort and investment from long-term innovation.

To ensure a robust pipeline, large medical device companies are instead investing in early stage companies, securing options to acquire them should they develop to fruition. Large companies are allowing acquired companies to retain more autonomy with technology and operations, and leveraging their established quality systems and supply chain to gain production efficiency.

> *Venture capital firms will continue to minimize their risk by providing less seed funding, investing in later stages, and steering exit strategies toward acquisition rather than IPO.*

Venture firms are rebalancing their portfolios, with greater emphasis on 510(k) submissions rather than Pre-Market Approval (PMA) applications. New rules from the FDA regarding 510(k) submissions could potentially tip the scales back to PMAs, which may afford better opportunity for differentiated value in the market.

During the financial crisis, less sophisticated venture capital firms dissolved, and the culling left the more experienced and robust firms standing. These remaining firms are comprised of partners with vast industry experience, and proven track records of start-up successes, which place them in a better position to fund start-ups of higher quality.

Despite funding challenges, MIS is still an attractive industry for venture investment but must maintain a reasonable return on investment lest VCs shift capital to alternative industries. Large companies must learn how to better manage innovation and cultivate the industry's financial strength. Future innovation may be driven by hybrid investment entities, where 'high risk, high reward' research is cultivated within a university setting, but supported by robust funding. The Wyss Institute of Biologically Inspired Engineering at Harvard University, founded by Don Ingber, the keynote speaker for this workshop, is an example of one such entity.

The Cost of Reimbursement

In the US, reimbursement coding helped standardize insurance coverage of existing procedures and devices. Unfortunately, reimbursement also inhibits innovation and instead encourages only incremental improvement of technology. New products or procedures seeking reimbursement must substantially differentiate themselves from predicate devices in terms of benefit and cost, but still must be similar enough to be categorized within existing codes.

There is little incentive for companies to commercialize new MIS technology and procedures if the codes do not exist. Existing codes in established markets have become budgets for device cost; a company must design the device to that budget to help drive profitability.

> *Reimbursement codes create narrow competitive markets that often devolve into market saturation and product stagnation.*

A company must pay close and early attention to its reimbursement strategy for a new product. Venture capital firms will turn away business plans if a reimbursement path is not well-defined. Large companies now treat reimbursement similarly to design and marketing requirements – projects are canceled early if reimbursement requirements cannot be met.

It is quite difficult to generate a new CPT code (Current Procedural Terminology) or DRG code (Diagnostic-Related Group) for reimbursement. New codes are typically driven by surgeons and surgical societies, with backing by industry. On the rare occasion, a large company can generate a new code if a compelling case is made, using multi-center studies with multi-demographic patient population and garnering consensus from multiple panels. Ultimately, the cost burden to back a new code will continue to drive companies to develop products within existing codes.

Globalizing Innovation

The majority of MIS companies will continue to follow the paradigm of developing devices in the United States, gaining CE mark and establishing initial revenue in Europe, and then building the revenue stream back in the US after obtaining FDA clearance. While early approval is possible in Europe, market uptake can be slow and in some cases lags US market uptake by several years.

To partly explain this phenomenon, the United States has a regulatory process focused on both safety and efficacy and maintains a highly restrictive reimbursement environment. In contrast, the European regulatory approval process focuses on safety, preferring to allow customers to select therapies based on efficacy. This should in theory lead to greater customer and patient choice. Instead, cost pressures in the EU have driven hospitals to select standardized therapies. This minimizes market choice. Meanwhile, in the US, there is significantly more choice among technologies after they clear regulatory and reimbursement hurdles.

New global players are not expected to significantly impact the US-Europe-US product launch model, particularly if various barriers continue to exist in international markets. China fosters research and development, but poor IP protection remains a major liability. India has better IP protection, but government bureaucracy prevents timely commercialization. US and European companies may do well to import technology or resources from China and India, but will likely not export IP-intensive development anytime soon.

Other global markets hold more promise for collaboration and development. In smaller markets like Australia and New Zealand, MIS companies are conducting more first-in-patient trials, taking advantage of progressive medical communities. In Japan, once new sophisticated medical technology clears stringent regulatory hurdles, it is well embraced by markets and insurance companies.

Israel will be a real hotbed for innovation in the coming decade – the World Economic Forum ranks Israel second in the world for the total funds raised by technology start-ups. Leveraging government incentives and university research, Israel already supplies high precision equipment to OEMs in Europe and the US. With many Israeli start-ups and OEMs soon to reach maturity, there may be collaboration and competition in European and US markets in the medium- to long-term.

A Surgeon's Perspective

Intra-operative Challenges

"Learning laparoscopic surgery is like crossing your arms on the steering wheel, looking in the rearview mirror, and trying to drive backwards," quipped one delegate.

Spatial orientation, accuracy, and repeatability remain key challenges in minimally invasive surgery. Surgeons need to know with confidence where the surgical instrument is within the body to monitor therapy delivery in real time. Orientation is further complicated because instruments often invert or rotate perspective, producing instrument movement that is counter-intuitive to hand motion. Additionally, when viewing the surgical field at high magnification, it is difficult for a surgeon to maintain the larger field of perspective of surrounding tissue and organs.

> *During an operation, a surgeon needs information from the surgical field with simultaneous microscopic and macroscopic perspectives.*

Current force actuation and manipulation performance appears to be sufficient for the requirements of robotic surgery. The force to cut tissue ranges from 1 to 2 lb-force and can easily be achieved by servomotors and simple mechanisms. However, for surgeries with semi-rigid or flexible instruments, actuation and manipulation remain challenging, especially as instrument size decreases.

A Steep Learning Curve

Technology that can enhance surgeon training is necessary for managing rapid uptake in the market and will help support consistency in surgical results.

> *For a newly developed procedure, operating surgeons either have specific skills or domain knowledge, but rarely do they have both.*

If either skills or domain knowledge are lacking, more training is needed to obtain proficiency for new MIS procedures, yet training costs time and money. Dozens or hundreds of training procedures are needed for an already competent surgeon to specialize in a new laparoscopic, endoscopic, or robotic procedure.

Training requires validation, and should reference the 'ideal surgeon' with cross-disciplined background as a baseline for assessment. This is necessary, since different surgeon groups have different expertise. General surgeons navigate around organs very well, but require time to familiarize themselves with laparoscopes and endoscopes. Laparoscope and endoscope specialists understand manipulation of tools, but tend to focus on confined spaces rather than surrounding organs.

Information Overload

Surgeons are like orchestra conductors; they are constantly monitoring the patient, equipment, their team's performance, as well as the instruments in their hands. As technologies and equipment integrate, the 'digital operating room' will become cramped. Information overload is a very real challenge, especially given that current consoles are already saturated with information.

The MIS industry generally lacks skills and knowledge in Human Factors engineering, a discipline of vital importance as newly integrated technology demands more sophisticated interfaces and information management.

Designing an appropriate user interface (UI) is becoming more complex. New technology must meet the needs of a broad consumer base – surgeons, interventional radiologists, nurses, technicians, and even field maintenance. Additionally, younger surgeons may be more receptive to new technology than more established surgeons. Delegates cited a case where a new product was released with an improved UI, only to find that surgeons preferred the legacy UI. Field modifications were necessary to revert the new product back to the legacy UI.

Technology Horizon

Integrating Imaging and Therapy

It is challenging and inefficient to diagnose during one procedure and treat during a second procedure. Technology should enable surgeons to diagnose conditions and deliver therapy simultaneously while still maintaining spatial orientation. Future products will derive less from a single technology, and more from the effective convergence of parallel technologies.

> *The integration of real-time multimodal imaging with therapy delivery will enable better surgical outcomes across multiple market segments.*

Software could add significant value in allowing overlay of multiple imaging modes, merging pre-operative and peri-operative CT, MRI, ultrasound, and thermography scans into a single stream of information during surgery. Hybrid OR suites are already seeing the first steps of imaging integration, enabling interventional procedures as well as open surgery in the same room at the same time. Real-time imaging during therapy could enable better and more efficient surgical planning and peri-operative decision-making.

Integrating imaging and therapy is not without its challenges. Validation and maintenance of new systems becomes increasingly complex, and the user interface must be carefully designed to present the right information to surgical staff in the OR. On the instrument front, developing surgical tools that are compatible with real-time MRI may saturate use of MRI machines in hospitals, creating backlog for diagnostic tests.

Radiation exposure management becomes a challenge when integrating imaging and therapy. Over-exposure is an increasing problem for the surgical team as intra-operative C-arm scanners are used more frequently. Some surgeons begin the operation keeping a disciplined distance from the radiation field, but then become engrossed in the surgical field and consequently risk over-exposure.

Training with Simulation

Simulation provides significant value for helping surgeons to rapidly familiarize themselves with a new procedure or new technology.

Simulators, unfortunately, are quite expensive and can impact a company's bottom line. Since the MIS industry generally pushes for lower cost, simulators are cost-prohibitive and unnecessary for certain markets. However, for high-value markets, such as robotic surgery, simulators can facilitate more widespread and rapid market adoption of radically new products.

What will simulators of the future look like?

Technology advances in accelerometers and MEMS chips from the gaming industry and consumer electronics may transfer into surgical simulators. However, technology transfer would be complicated. Most video games are based on 'twitch' control while surgery requires smoother control for tissue cutting and manipulation.

Flight simulators are quite advanced and accurate; astronauts land the space shuttle having only practiced in simulators. Mathematical models for flight exist and are well understood; however, accurate models of pathologic and physiologic tissue behavior are still needed for surgical simulators. Additionally, flight simulators focus on teaching pilots what to do when things go wrong, while surgical simulators traditionally focus on teaching surgeons how to do things right. Surgical simulators could add further benefit to training programs by incorporating more emergency response challenges.

A Touch of Haptics

"Using a flexible endoscope feels like pushing rope into an empty room," lamented one delegate. Can haptic feedback solve this problem? With most systems requiring expensive and custom fabrication, the cost of implementation does not easily translate into patient benefit. Also, surgeons already learn to use visual feedback to replace the lost sense of touch in MIS procedures. Still, haptic feedback could add value to specific procedures, primarily through reducing the learning curve and augmenting the surgeon feedback loop.

Ripe for Technology Transfer

Different industries have solved problems similar to those that MIS faces. Could MIS companies learn anatomic navigation from oil exploration companies?

More broadly, our delegates examined existing technologies that could apply to MIS instruments and equipment, and predicted the following possible technology transfer areas:

Industry	Technology	Use in MIS
Telecoms	Optics Technology	Improved imaging fidelity
Aircraft	Simulation	Improved training
	Quality Management	Better risk management and efficiency practices
Defense	User Interface Standards	Improve flow of information to surgeon
	Decision Support Software	
	Human Factors Engineering	
Consumer Electronics	Accelerometers	Haptic feedback
	MEMS	Chip-on-tip visualization
	3D Experience	Pre-operative planning
Material Sciences	Ceramics and Plastics	MRI-compatible instruments
	Radio-luminescence	Improved imaging
	Cost-efficient Materials	Disposables design

Resources for the Future

MIS has traditionally been a mechanically orientated industry. As imaging and visualization integrate with therapy, companies will seek greater skill depth in software and electrical engineering, system integration, and quality and risk management. Human Factors Engineering will play a major role in ensuring the seamless interface between human and machine, and will serve to improve workflow, reduce risks, surgery time, and training time.

MIS companies also need to change from the top as much as from the bottom. Management and boardrooms need more experience in system integration to aid better strategic decisions for new products. Additionally, greater emphasis is needed for improved education and collaboration with regulatory authorities on software validation and user studies.

New Markets

Targeting Underserved Markets

Neurological and cardiovascular MIS markets continue to experience strong growth, as they offer a significant value proposition compared to open surgery, especially for high-risk patients. In particular, intervention solutions for the obese are expected to show high growth. Obesity is endemic in the US and United Kingdom, and there is an urgent clinical and societal need to establish early and safe intervention or prevention.

In the medium- to long-term, MIS could provide new options to previously unpenetrated markets such as metabolic diseases. Various gastro-intestinal interventions are in clinical trials to demonstrate remission or even reversal of Type II diabetes. If these procedures prove successful, MIS techniques could offer a low-risk surgical option to bariatric surgery.

MIS treatment of endocrine system disorders is already in use for removing tumors from thyroid and adrenal glands. There has been substantial growth in ablative and embolic procedures to treat tumors where image guidance is key to delivering intervention accurately. For other cancer treatments, MIS technology could pair well with nano-particle injections or targeted therapy to provide accurate delivery to the pathological site.

Natural Orifice Surgery – Here to Stay?

Clinical demand for Natural Orifice Surgery (NOS) appears to be minimal for the short term. Procedures are still quite complicated for surgeons due to limited operating space. Generating the forces needed for tissue resection or retraction is restricted, and closure continues to be hindered by lack of proper visualization.

> *NOS companies should focus on addressing unmet clinical needs rather than competing with established laparoscopic and endoscopic methods for existing procedures.*

Companies are essentially waiting on the sidelines until demand increases and the technology proves its clinical value. Despite its challenges, the potential benefits of NOS still remain attractive. If in-hospital recovery time can be reduced from one week for general surgery to two days for laparoscopic surgery and to several hours for NOS, then there may be significant value.

NIS is the New MIS

Throughout history, as precision technology matured, surgeries transitioned to less invasive procedures. Therapies that started as total knee replacements evolved into knee resurfacing, and now use hyaluronan injections for treating osteoarthritis. There is no question: Non-Invasive "Surgery" (NIS) is on the rise.

Despite the shift of patient care from large centers of excellence to local specialized care hospitals, new capital intensive technologies for NIS will continue to emerge in the large centers first. As an example, proton beam therapy may be an eventual replacement for radiation treatment for certain pathologies. However, proton beam therapy requires upwards of $100 million in equipment, and there are only several dozen centers in the world that currently perform this procedure. Also, long-term outcomes of proton beam therapy compared to radiation are still being debated.

> *Treatment is continually moving upstream, from curative to preventative medicine. MIS offers low risk alternatives to open procedures for patients seeking preventative treatment.*

More widespread in patient care, there is a shift from resective surgery to ablative surgery. Instead of cutting out cancerous tumors, surgeons are vaporizing them. High-Intensity Focused Ultrasound (HIFU) allows pathological tissue to be heated very precisely and destroyed. The technology does require further characterization, as uncontrolled micro-bubble cavitation can damage tissue. Still, HIFU shows great promise for multiple applications, as does radio-surgery, another non-invasive surgical option.

Enabling a New Health Paradigm

The integration of technologies and services will transcend the operating room. New diagnostic instruments and assays will provide earlier warning for diseases, affording opportunity and demand for earlier intervention. Advances in biologics, stem cell research, and regenerative medicine will require novel systems for delivery within the body. Tissue engineering and gene therapy will introduce an entirely new facet to surgical practice. There is significant opportunity for synergy and partnerships between industries; hesitation in engagement could result in greater competition rather than collaboration.

The convergence of surgery with pharmaceutical, biotech, and diagnostic technologies will ultimately create better clinical outcomes with lower risk. The MIS industry is well positioned for growth, and will be an enabler of a new health paradigm of earlier intervention for prevention of diseases.

About Cambridge Consultants

Cambridge Consultants has, for 50 years, enabled its clients to turn business opportunities into commercial successes, whether launching first-to-market products, entering new markets or expanding existing markets through the introduction of new technologies. We develop breakthrough products, create and license intellectual property, and provide business consultancy in technology-critical issues for clients worldwide.

With a team of nearly 300 engineers, scientists and consultants, in offices in Cambridge (UK) and Boston (USA), we offer solutions across a diverse range of industries including medical technology, industrial and consumer products, automotive, transport, energy, and wireless communications.

Medical technology is a core strength of our business. Within this industry we specialize in four areas, namely diagnostics, drug delivery, surgical and interventional products, and wireless medical technologies. Within these areas our work ranges from concept development through to turnkey device development, and encompasses skills including product design, analysis, low-cost electronic design, regulatory affairs and program management. Further information about our work in these areas can be found on our website.

As part of our ongoing commitment to the MIS market, we would be pleased to hear your feedback on the content of this report, and to discuss your views on the future direction of the industry.

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For further information or to discuss your comments, please contact:

info@CambridgeConsultants.com

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Cambridge Consultants Ltd
Science Park
Milton Road
Cambridge
England CB4 0DW

Tel +44 (0)1223 420024
Fax +44 (0)1223 423373

Cambridge Consultants Inc
101 Main Street
Cambridge MA 02142
USA

Tel +1 617 532 4700
Fax +1 617 532 4747