MAPPING THE FUTURE

magnetecs
guiding medical technology

MAPPING THE FUTURE
“The harmony of the world is made manifest in Form and Number, and the heart and soul and all the poetry of Natural Philosophy are embodied in the concept of mathematical beauty.”

– Sir. D’Arcy Wentworth Thompson (1860 to 1948)
Biologist and Mathematician
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Magnetecs Corporation is an advanced medical device company that is pioneering unique and highly effective technologies in order to give the physician greater control and agility in dealing with serious disease issues where the use of precision catheter placement is required for a successful outcome. Through the use of our robotic catheterization control systems for minimally invasive procedures, proprietary designed catheters tailor-made for specific treatment applications and the potential co-venturing with proven strategics where our precision guidance systems can be used to exponentially enhance the delivery and therefore effectiveness of their treatment systems, Magnetecs is paving a new path for providing a vast array of patients with chronic and often life-threatening diseases greater hope, lower treatment cost and better quality of life.

**OUR COMPANY**

Magnetecs intends to be a global leader in the development of advanced medical technologies utilizing robotic control and electromagnetic navigation methodologies that increase the efficacy and efficiency of physicians performing minimally invasive procedures in areas such as cardiology, gastroenterology, neurology and gynecology and more. The Company’s products, both existing and under development, can increase the proficiency of physicians and improve the efficiency of hospitals and clinics. The multiple benefits of the Company’s electromagnetic guidance and control systems, and advanced catheter toolsets are expected to dramatically reduce the cost of healthcare by bringing safer, more effective and efficient treatment methods to an ever increasing number of patients.

**OUR MISSION**

The Company is focusing initially on the treatment of atrial fibrillation (AFib), a common form of heart arrhythmia which currently affects 2.2 million Americans and more than 5 million individuals globally. It is anticipated that in the U.S. alone this number will increase by at least 160,000 new diagnoses each year. Recent market studies estimate that approximately 200,000 AFib-related EP procedures are performed each year in the U.S., and this number is expected to grow to 400,000 by 2014. Within the coronary catheter market, AFib is the fastest growing segment and with approximately 220,000 ablation and mapping procedures in the U.S. each year, this healthcare segment represents a potential $1 billion market. As we near global certification and commercial acceptance of our technology in this area, we will begin to expand our efforts into other areas of disease treatment.

**OUR FOCUS**

With ISO and CE Certification already acquired and three CGCI Operating Suites for the treatment and study of AFib catheter ablation, Magnetecs intends on expanding market penetration and viability confirmation through additional CGCI installations in key global locations which will allow the company to continue to pursue additional human trials in order to complete and acquire FDA approval for U.S.-based installations.

In addition, Magnetecs will begin to pursue the commercialization of its MOSFET (Metal-Oxide Semiconductor Field-Effect Transistor) catheter technology for various electrophysiology uses including Renal Denervation procedures and Implantable Cardioverter Defibrillators (ICDs). Currently ICDs comprise a $7.8 billion market and Renal Denervation is expected to exceed $2.5 billion market share by 2020. Magnetecs’ MOSFET technology has the potential to fundamentally change the usage of catheters, pacing leads, and other devices used for these procedures in addition to other applications.
“If I have seen further, it is by standing on the shoulders of giants.” So world-renowned author and Bishop John of Salisbury stated in 1159 in his book *Metalogicon*. Indeed most advances in the arts, sciences and the humanities are a result of building on the works of those who came before. Still, once in a great while, there are those who are willing to not merely stand, but to leap from those shoulders and in their boldness discover new frontiers that exponentially advance the realms of possibility.

Magnetecs Corporation represents the results of just such a leap of faith. Founded in 2003 by four individuals, each highly accomplished in their individual areas of endeavor, they established Magnetecs to bring to the world a bold solution in the advancement of disease treatment solutions where catheter-based, noninvasive surgery is required. Cardioablation, gastroenterological exploration, endovascular surgery, cerebral aneurysms, urologic and gynecologic disease are just some of the areas where the use of manually-guided catheters are required.
Understanding the problem
Although physician-guided, catheter-based disease treatment has become a growing and accepted standard for procedures such as Atrial Fibrillation (AFib) ablation, endovascular coiling, transurethral prostatectomy and endoscopic exploration, such procedures do not come without significant risk. These risks can include minimal effectiveness requiring repeat procedures, vascular injury, organ perforation, blood clotting, septic infections, stroke and even death.

Key to the effectiveness of physician-guided catheter procedures is the ability of the physician to accurately position the catheter tool “on-site” where it is needed while minimizing invasiveness to the patient’s system and optimizing the results for a positive patient outcome.

In procedures where distance from the catheter insertion point to the treatment site is short, the channel is relatively large and the target area can be easily visualized, these risks are significantly low, such as the resection of the prostate gland. When any of these parameters change, the risk increases exponentially.

The ablation of AFib (see The Truth About AFib for more), is just such a case. To treat AFib using catheter ablation, a catheter must be guided from an insertion point in the groin or neck of a patient, through the arterial network and into a chamber of a beating heart where it must then precisely “ablate” or destroy portions of tissue in order to lessen or eliminate the recurrence of AFib.

For over twenty years, procedures like this have relied solely on the skilled hand of the physician manually navigating the catheter using a two-dimensional imaging visualization aid such as an X-ray or fluoroscope. The risk potential is obvious when the environment the physician must traverse is not only three-dimensional, but a moving target as well, as is the case of placing a catheter in a specific chamber of a living, beating heart and then manipulating the catheter to precisely ablate multiple sections of the heart tissue in order to correct cardiac arrhythmia.

Finding the solution
It was this specific problem, as well as the global issue of catheter navigation that first sparked Magnetecs’ Co-founder, Chief Executive Officer and Chief Innovation Officer Josh Shachar to ask, “Is there not a way in which we can give a physician a tool that allows them to be in harmony within the environment with which they are working instead of being a third-party observer outside of the realm in which they are trying to affect a cure?” In other words, was there a way to allow a surgeon to be as virtually “inside” the area of operation as they are physically “inside” an operating room? A way to allow the doctor to work in tandem with the three-dimensional living body in order to more effectively treat his patient?

As with all engineering problems he had faced before, Josh’s philosophy was to look to nature for a solution.

“In nature we can observe how even the most complex of systems when examined closely, breakdown to very simple and fundamental systems of interaction; cause and effect.” – Josh Shachar

The Founding of a Game changer
If the success of a company was solely a result of the uniqueness of its product or service, there would be a lot more Apples and Googles in the world today. But as anyone can tell you, it is not just a great product that makes a great company, it is the visionaries and the people who stand behind the product that truly make it a success. Magnetecs was founded by four very skilled, dedicated and innovative minds that have helped take the company from an idea to a potential game changer in the field of magnetic controlled guidance systems in the advanced medical device marketplace.

Josh Shachar
• Inventor
• Entrepreneur
• Innovator
• Business Exec.
• Creator of over 100 patents

Dr. Eli Gang
• Clinical Electrophysiologist
• Board Certified: Internal Medicine Cardiology
• Voted one of the U.S.’s Top Doctors

Eytan Lombroso
• Business Exec.
• Global Financial Experience
• Expert in Strategic Growth
• Creator of high performing businesses

Frank Adell
• Business Exec.
• Two decades developing high technology companies
• Has worked with several Fortune 500 Companies
we can observe how even the simplest process, such as gravity moving molecules of water from a high elevation to a lower plateau can start a chain of interactive and synergistic processes that eventually lead to the creation of a marvel such as the Grand Canyon with all its rich biologic, geologic and ecologic complexity.”

With this in mind Josh looked to his decades of experience in developing guidance systems for the U.S. Department of Defense (DOD) where he had been behind the innovation of many of our nation’s weapon system guidance technologies. Using the experience he had gathered from these endeavors and simply seeing that the issue, and therefore the solution were simply a matter of scale and environment, he began to assemble a team to seriously tackle the problem.

The team quickly settled on the concept of using opposing magnetic force fields as the basis for controlling an object’s position in three-dimensional space. In 1996, Josh filed the first patent for their developing technology titled “Method and Apparatus for Catheter Guidance Control and Imaging.”

Catheter Guidance Control and Imaging, or CGCI for short, was developed on the premise of creating a robotic-controlled platform using magnetic force for the remote navigation to guide surgical instruments within a patient’s body.

**Magnetecs – bringing CGCI to life**

Over the next seven years, Josh and his team brought the concept off the paper and into reality. In 2003, Magnetecs Corporation was founded by Josh along with Frank Adell, a top executive with over 20 years of experience in strategic planning and marketing development for technology startup companies; Dr. Eli Gang, MD, FACC, FACP, a Clinical Professor of Medicine at the UCLA Medical School and the Director of the Clinical Electrophysiology Laboratory at Brotman Hospital in Los Angeles; and Eytan J. Lombroso, a business executive with over thirty years’ experience in finance, global banking and creating high profitability growth businesses. Together they began to assemble a team of top research scientists, mechanical and software engineers to take CGCI from its early prototype design into a complete operational system in order to begin the long road to certification and commercialization.

In addition, an executive management team was formed and a Clinical Advisory Board that included some of the best-known physicians, scholars and researchers in the areas of Cardiology, Electrophysiology and Internal Medicine was brought together to provide objective review, protocol recommendations and development strategies.

Within four months of incorporation, Josh and his team had constructed the first working prototype of CGCI. The unit used a series of four 2” magnetic lobes and basically provided the team validation of the assumptions made in the 1996 patent regarding the ability to control an object in three dimensions using a variable magnetic field array. With this hurdle crossed, the challenge became how to scale the machine to a size that would be serviceable to work within a human body. As magnetic field laws do not work in a linear fashion, that is, if you want to make a magnetic field twice as strong you cannot just double the power and size of the structure, solving the scalability problem became a daunting issue. Fortunately, this was an area Josh had been dealing with over the past ten years. In his efforts to optimize radar and guidance systems for the DOD, Josh had discovered a unique method for “lensing” or focusing magnetic energy in a manner that maintained the power of the field in a controlled beam over a greater distance using less power than was previously possible. Although at the time, his proposal of this technique was laughed at by several of his counterparts at General Electric...
Aviation Division as being unworkable, Josh knew that his theory could dramatically shift the field of magnetic guidance.

Over the next five years, the team was able to prove Josh’s magnetic field lensing theories correct as they built first a 4” and then an 8” model of CGCI. Each one using a fraction of the energy to generate and hold a stable magnetic field in place. During this time, the team was also developing proprietary interface for the imaging and guidance systems that would be used to control a full-scale CGCI unit.

Finally in early 2007, with the scalability issues solved and several major advancements in the technology finalized, the team was ready to construct a large-scale CGCI unit that could be used for its first step towards commercialization; clinical animal studies.

CGCI-I was built to meet this purpose. It was a 2/3rd scale model of the system and now incorporated an array of eight magnetic lobes for more precise control as well as a complete suite of imaging, monitoring and control surfaces that would allow a physician to operate the entire system from a remote control suite adjacent to the operating theater and have real-time three-dimensional imaging of the area the physician was working in as well as continuous monitoring of the patients vitals and other biometrics.

The First Studies
In November of 2007, Magnetecs entered into its first large animal study. The study consisted of 15 subjects undergoing a simulated AFib procedure to show the ability of CGCI to move a catheter to an identified target site, remember the location and then return automatically to the site on a repeated basis. The study also tested the ability of the CGCI to perform a simple Atrial Ablation procedure. The study performed at Cedars Sinai Hospital in Los Angeles, CA from November of 2007 to May of 2008 under the direction of Dr. Eli Gang was an overwhelming success and proved CGCI was on track to meeting all the benchmark goals the company had set for itself in moving the technology forward to certification.

The success at Cedars Sinai opened the door for the company to begin the long path to the myriad regulatory compliance certifications that would be required as they moved to commercialization. The first of these was USDA authorization to perform independent animal studies under the Magnetecs umbrella, which was granted in August of 2008. With this certification in hand, Magnetecs was able to perform a series of in-house “wet-lab” studies to further refine the CGCI technology.

Next, UL Certification was granted to the company on September of 2009 bringing them into compliance with all requirements as an approved electrical device for use in the medical field. In July of 2010, Magnetecs received its ISO-13485 Certification which verified CGCI’s adherence to International Standards of Safety and Quality as a medical device.

Human Trials
Magnetecs was now ready to begin the first-in-man clinical trials. A full-scale model of the CGCI called CGCI II was constructed and the protocols for the human trials were finalized. It was decided

**The Path to CGCI**

CGCI represents a quantum leap forward in a variety of areas including scalable controlled magnetic lensing, precision control of the movement of an object in three-dimensional space using variable field magnetics and the ability to do this with lower levels of input power, greater reclamation and regeneration of the magnetic field wave - all at a minimum risk exposure to the patient. What was thought impossible just 20 years ago, Magnetecs has made a reality that has the potential to benefit the lives of countless patients where this technology can be more effective, more cost-efficient and more reliable in order to provide a better solution.

**CGCI – P1**
First prototype to measure baseline magnetic field density “pole to pole” in a two-dimensional environment.

- **Size:** 4”
- **Number of Coils:** 4
- **Size of Coil:** 2”
- **Input Power:** 120v
- **Output Power:** 500 Gauss

**CGCI – P2**
Second prototype to measure magnetic field density at center focal point of coils in a three-dimensional environment. The resulting data allowed for the scalability issues associated with building CGCI to be solved.

- **Size:** 4”
- **Number of Coils:** 6
- **Size of Coil:** 2”
- **Input Power:** 120v
- **Output Power:** 500 Gauss

**CGCI – I**
The first fully operational model of the current 8-lobe model. This unit, built at 2/3rd scale, was used for the initial animal testing at Cedars Sinai.

- **Size:** 4”
- **Number of Coils:** 8
- **Size of Coil:** 18”
- **Input Power:** 15,000 watts
- **Output Power:** 900 Gauss

**CGCI – II**
CGCI-II is the current full-scale, fully operational unit being marketed by Magnetecs. The unit is now in operation in four countries and more sites are scheduled to come online.

- **Size:** 4”
- **Number of Coils:** 8
- **Size of Coil:** 24”
- **Input Power:** 50,000 watts
- **Output Power:** 1900 Gauss
to conduct the study at the prestigious University Hospital of La Paz in Madrid, Spain. Under the direction of Principal Investigator Dr. Jose Merino, Director of the Arrhythmia and Electrophysiology Research Unit of the hospital and with the assistance of Dr. Gang, the first phase of the study consisted of 20 patients in which a highly detailed map of the heart would be created along with specific key target points within the various chambers being identified. Once completed, the catheter was removed to its starting point and then guided robotically by CGCI back to the heart and to each identified target location. The CGCI-II Electrophysiology (EP) Suite was installed and tested in June of 2010 and the trials began immediately thereafter.

The results of Phase One testing was successfully completed in January of 2011 and Magnetecs immediately moved into Phase Two trials of the human study. The Phase Two diagnostic expanded the study to an additional 20 patients undergoing the same test protocols. Again the results proved CGCI could outperform any existing robotic system on the market in its ability to track, target and return to target on a repeated basis in less time and with less post procedural side-effects.

Magnetecs’ next step was to prove the ability of CGCI to successfully perform an arterial ablation procedure. A Phase Three study consisting of 56 patients with diagnosed AFib was constructed. The goal of the study was to perform a series of atrial ablation procedures in which 18 were paroxysmal atrial ablations. The study showed a dramatic 80% efficacy rate. The trial was completed successfully in December of 2011 at which point Magnetecs applied for CE Mark certification which would allow the company to begin commercial sales of CGCI in the European Union (EU).

In October of 2011 Magnetecs received its IEC 60601-1 Second Edition Certification for CGCI. Issued by the International Electromechanical Commission, the IEC Certification validated CGCI as being a fully compliant and safe device not only for general medical use but also for all safety and performance requirements for Electromagnetic Compatibility devices.

Due to the success of the first set of trials, Magnetecs began to see growing acceptance of the CGCI technology as physicians and media representatives from all over the EU were able
to review the data and actually see the unit in operation. Magnetecs received a citation of merit from Madrid’s President Esperanza Aguirre. Dr. Merrino was asked to do a “live-case” presentation for the European Heart Rhythm Association (EHRA) at their annual Eurospace convention, and the company and La Paz Hospital received multiple articles, announcements and TV news coverage in both local and international press.

**CE Mark and New Installations**

With the completion of the first three human trials in Madrid, CGCI was well on its way to becoming not only a viable method of treatment for AFib, but potentially the preferred method. Magnetecs was contracted to install its next CGCI-II EP suite at Yonsei University Hospital in Seoul, Korea. The installation was completed in October of 2011 and was placed under the direction of Dr. Huy Nam Pak, Director of Electrophysiology for the hospital, to begin the process of gaining approval from the Korean Food and Drug Administration (KFDA) in order to begin Asian Pacific Trials.

In December of 2011, Magnetecs received its CE mark designation for CGCI-II and began evaluating proposals for deployment of additional CGCI-II EP suites within the EU. Sites in contention included both the Na Homolce Hospital in Prague and the International Clinical Research Center of St. Anne’s University Hospital in Brno, Czech Republic; the Rambam Healthcare Facility in Haifa, Israel; the Sapienza University in Rome, Italy; and the Hammersmith Hospital in London, England. In addition, with the EU market now in place, Magnetecs was posed to begin the process to being granted FDA (510K) Certification to allow the company to begin installations in North America. Requests for CGCI-II EP Suites had already been received from various major medical institutions including the Utah Valley Regional Medical Center in Provo, UT, the General Hospital in Montreal, Quebec, Canada as well as four CGCI-II EP Suites for Mount Sinai Hospital in New York, NY.

**The New Economic Reality**

During 2012, the results of the global economic downturn effectively dragged to a standstill the ability for most growing advanced medical device companies to achieve any ground in market share as hospitals, research universities and the entire medical field was faced with the need to dramatically cut costs and budgets for not only new development but for core programs as well. Magnetecs was not immune to this new fiscal reality. Rather than abandon its efforts, the management team believed that the temporary reverse in economics could be used to the company’s advantage.

Magnetecs underwent a thorough re-organization of the entire company to make it leaner and more agile for the new economic reality. It re-evaluated all existing relationships and contracts with strategics and vendors as well as re-negotiated relationships with its partners that would be favorable to not only staying viable during this period but poised for dramatic growth once the economy turned around.

The management team also remained on a continued validation and market acceptance program for CGCI-II through further clinical human trials in Madrid, the training and education of the Yonsei University staff in preparation for clinical trials in Korea, and on-going lectures and meetings with regional hospital administrators and decision makers as well as seminars and case study presentations with noted EP and Cardio specialists around the world.

**MOSFET**

2012 also marked the launch of Magnetecs’ development for a corollary catheter product they called MOSFET (See MOSFET – A New Lead on Life). MOSFET represented another pioneering leap forward in Josh Shachar’s ongoing quest to “do it better”. The MOSFET technology was designed to dramatically improve the quality of internal site-mapping as well as improve the precision of ablation treatments for conditions such as AFib and Hypertension where Renal Denervation is the preferred method for treatment. MOSFET was a natural “hand-in-glove” fit to CGCI technology as well as providing the entire EP and Cardiac medical community a vastly improved toolset to work with even where a CGCI-II EP suite was not available.

With an addressable market of $3.9 billion globally, the entry into the disposable catheter market for pacing leads, pacemakers, Renal Denervation, RF mapping and ablation was a perfect companion venture for the company. By September of 2012, Magnetecs had created its first MOSFET Pathfinder prototypes. The results of the first set of non-clinical tests showed that MOSFET demonstrably outperformed the standard decapolar catheter in terms of resolution, signal fidelity and sample rate.
With this success in hand, research and development of an array of MOSFET Catheters was undertaken. As a result of this research, Magnetecs applied for and received over seven patents related to the MOSFET IP. The company plans on creating and launching a separate division of Magnetecs to handle the further R&D, regulatory hurdles and marketing for this remarkable advance in catheter technology.

**CB Mark and Magnetecs Turns a Corner**

As the downturn continued to hold back business expansion across most market sectors in 2013, Magnetecs continued to hold the line on making sure it remained fiscally stable while continuing to explore new partnerships, continued research and quality assurance of its CGCI technology and the broadening of its patent set for MOSFET.

In October of 2013 Magnetecs’ applied for its IEC 60601-1 Third Edition Certification for CGCI. As of this moment, most of the Certification has been approved and it is anticipated to be finalized by the end of 2014. In addition, the company applied for and received its IECEE CB Certification. Like the CE mark which allows a company to market its product within certain EU countries, the CB Certification opened the door for Magnetecs to now market CGCI in a multitude of Asian, South American and non-EU Western European countries.

As 2014 started to see the economy in the medical device and research fields begin to climb back up, Magnetecs finalized its contract to install the next CGCI-II EP Suite in the Na Homolce Hospital in Prague, Czech Republic. Under the direction of Dr. Petr Neuzil, Head of Cardiology for the Hospital, and Dr. Vivek Reddy, Professor of Medicine and Director of Cardiac Arrhythmia Service at Mount Sinai School of Medicine, in New York City, the Prague installation’s first project would be to take part in a multi-site randomized study of paroxysmal atrial ablation procedures with 100 patients using protocols and standards that would match or exceed EU and FDA requirements. It is hoped that the resulting dataset from the trial will not only provide further commercial validation amongst the CGCI approved countries, but also help provide base data that will smooth the path to U.S. FDA (501K) Certification.

All the components for the CGCI Suite were shipped to Prague in September of 2014 and the suite was officially opened on October 10, 2014.

As 2014 draws to a close it is anticipated that final KFDA Certification will be issued, along with final IEC 60601-1 Third Edition Certification for CGCI. With these in place, both the Korean and Multi-site clinical studies are set to commence within the first quarter of 2015.

What lies in the future for Magnetecs? With a steady growth in economic indicators in the medical sector, an increase in the need for cost-effective, efficacious treatment methodologies for catheter-based noninvasive surgeries for an expanding population whose lives can be saved by such measures, it seems Magnetecs is perfectly positioned to not only chart a course for the future of this market, but to lead the way for others to follow.

“At the core of any task is the fundamental and unassailable belief that a solution is possible.”

– Josh Shachar
“Wherever the art of Medicine is loved, there is also a love of Humanity.”

– Hippocrates
a Timeline of Achievement

For almost two decades, the vision for Magnetecs has been one of building a strong company based on a solid and innovative technology platform that is backed by a team of strong leadership and visionary innovators from a variety of science, engineering and medical fields who all come together to bring cutting edge solutions that will enhance the ability of the physician and increase the safety and well being of the patient.

1996
- Josh Shachar files first patent for “Method and Apparatus for Catheter Guidance Control and Imaging.”
- Magnetecs Corporation is founded by Josh Shachar, Dr. Eli Gang, Eytan Lombroso and Frank Adell
- Dec. 31, 2003 – Magnetecs files nine patents over the course of the preceding year relating to its CGCI apparatus method as well as the system and method of radar-assistance.

2003
- CGCI P1 and P2 Prototypes built to validate concept and solve scalability issues.
- May 27, 2003 – Magnetecs files patent #11/140,475 describing CGCI’s proprietary methodology for shaped magnetic field control.
- Dec. 31, 2004 – Magnetecs files seven patents over the course of the preceding year relating to CGCI’s method and system of radar-guidance.

2004
- Dec. 31, 2006 – Magnetecs files nine patents over the course of the preceding year relating to CGCI’s method and system for controlling movement of surgical tools, generating a magnetic field, the magnetic catheter tip and shaped magnetic field control.

2005
- 2/3 scale model of CGCI unit built.
- Nov. 1 2007 – Magnetecs conducts first large animal study at Cedars Sinai
- Dec. 31, 2007 – Magnetecs files nine more patents over the course of the preceding year relating to CGCI’s apparatus, method and system for radar-assistance as well as the MOSFET sensor apparatus of the magnetically deployable catheter with the sensor and method for mapping and ablation.
• Dec. 31, 2008 – Magnetecs files nine patents over the course of the preceding year relating to the apparatus and method for controlling catheter positioning and orientation, the magnetic linear actuator for deployable catheter tools, the Lorentz-Active sheath display and control of surgical tools, and creating a high resolution map of electrical and mechanical properties of the heart. All of these continue to build and enforce the Magnetecs IP portfolio.

• May 2010 – Full scale model of CGCI unit built.

• Jun. 2010 – CGCI suite built and 20 patient human trial begins at University Hospital of La Paz in Madrid, Spain to study navigational capabilities of CGCI.

• Jul. 2010 – Magnetecs received ISO-13485 Certification which verified CGCI’s adherence to International Standards of Safety and Quality as a medical device.

• Dec. 31, 2010 – Magnetecs files eleven patents over the course of the preceding year relating to the apparatus and method for the Lorentz-Active sheath display and control of surgical tools, creating a high resolution map of electrical and mechanical properties of the heart, magnetic waveguide formation for shaped field employing magnetic aperture, and acquiring high density mapping data, simulation training, targeting catheter electrodes, using tissue contact information in the automated mapping of coronary chambers employing magnetically shaped fields as well as diagnostic, therapeutic, and method of magnetic propulsion capsule.

• Sept. 2009 – UL Certification granted, giving approval for CGCI use in medical field.

• Dec. 31, 2009 – Magnetecs files ten patents over the course of the preceding year relating to the apparatus, method and system of the MOSFET sensor, the Lorentz-Active sheath display and control of surgical tools, creating a high resolution map of electrical and mechanical properties of the heart, a catheter impedance seeking device, acquiring high density mapping data, simulation training, and targeting catheter electrodes. In addition to CGCI, Magnetecs files 2 additional MOSFET patents relating to the apparatus of the magnetically deployable catheter with the sensor and method for mapping and ablation.

• Jan. 2011 – Phase 1 Human Trial Study completed in Madrid.

• Feb. 16, 2011 – Magnetecs files a unique patent for CGCI related to the method and system for using tissue contact information in the automated mapping of coronary chambers employing magnetically shaped fields.

• Feb. 2011 – 20 patient Phase II Trial started in Madrid to expand on results of Phase 1 study.

• Jul. 2010 – Magnetecs received ISO-13485 Certification which verified CGCI’s adherence to International Standards of Safety and Quality as a medical device.

• Sept. 2011 – 54 patient Phase III Trial begins in Madrid to perform standard atrial as well as paroxysmal atrial ablations.

• Oct. 2011 – Phase III Human Trial is completed.

• Oct. 2011 – Magnetecs received IEC Certification validating CGCI as a fully compliant and safe device.

• Oct. 2011 – Second CGCI suite completed at Yonsei University Hospital in Seoul, Korea.

• Dec. 2011 – Magnetecs received CE mark designation for CGCI.


• Mar. 2012 – Magnetecs begins development of MOSFET, a corollary catheter product.

• Sept. 2012 – MOSFET Pathfinder prototype created.

• June 15, 2012 – Magnetecs files a patent related to MOSFET’s apparatus and method for a magnetically guided catheter for renal denervation employing the MOSFET sensor array.

• Sept. 17, 2012 – Magnetecs files patent #13/621,727 establishing further IP for MOSFET’s ability to measure biopotential and map emphatic coupling employing a catheter with a MOSFET sensor array.

Atrial Fibrillation (AFib) is an exponentially growing health concern in the U.S. that strikes at the one human condition we cannot avoid: getting older.

AFib is a disease that manifests itself as an irregular heartbeat that occurs when the heart’s electrical system is not working properly to coordinate the task of pumping blood throughout the body. Counting for more than 350,000 hospitalizations per year in the U.S.1, this electrical misfiring of the heart causes the organ to flutter inefficiently which allows blood to pool or clot. About 35% of all AFib patients will have a stroke at some point in time1, which occurs when a blood clot breaks off and becomes lodged in an artery leading to the brain. As the brain is unable to receive oxygenated blood, loss of brain function can occur due to hypoxia and if not treated quickly, can result in permanent brain damage and even death.

Unfortunately, the causes of AFib are still being researched and there are no conclusive indicators. There is clear evidence that the chances of contracting AFib increases as you age with the diagnosis occurring in approximately 4% of the U.S. population over 60 years of age and 10% for those around 80 years of age. The median age of AFib diagnosis for men is almost 67 and for women it is about 75. There are also several risk factors that are being investigated, such as thyroid disease, hypertension, heart disease, obesity, stress, lack of exercise and stimulants such as caffeine.

Many AFib diagnosed patients are unaware of the severity this condition can cause and there are many more that go undiagnosed as they do not display common symptoms such as rapid heartbeats exceeding 200 BBM, irregular stutters in the heart, as well as fatigue and shortness of breath. Furthermore, AFib can be a singular, one-time occurrence whose effects can cause the same significant damage as those who suffer chronic AFib. Those with AFib are not only more likely to suffer from a stroke, but these AFib related strokes are three times more likely to be fatal. About 88,000 deaths a year are attributed to AFib and the death rate for women with this condition is 2.5 times greater than those of men with it.

The cost of treating AFib is estimated to be approximately $6.65 billion in the U.S. per year including direct and indirect medical costs such as procedures like catheter ablation and pacemakers, costs of drugs and other treatment materials such as beta-blockers and antiarrhythmic drugs, cost to patients family members for adapting to new lifestyle changes which includes insurance, lifestyle and on-going self-treatment costs.

Managing a healthy weight through a balanced diet and exercise will increase the strength of your heart and curb obesity while also decreasing your stress and anxiety levels as well as your chances of contracting other risky heart-related diseases. However, lifestyle changes can only help with so much and proper diagnosis and treatment of cardiac disorders is extremely important. An ECG is used to identify the waveforms of your heartbeat so that a doctor can visualize the amplitude, shape and timing of them to see if there are any irregularities. Medications might be prescribed to treat the initial diagnosis and typically focus on controlling the rate and rhythm of the heart. Rate control slows the heartbeat and rhythm tries to maintain a steady beat in order to stop fibrillation (sudden irregular flutters). These changes in lifestyle and medication are the ideal first steps, but for more urgent cases minimally invasive procedures such as catheter ablation are the accepted next step in trying to deal with this life-endangering problem. In extreme cases, open-heart surgery is necessary, but the risk and complications associated with this become very high, as does the pre- and post-operative expenses.

With catheter ablation, the procedure involves insertion of an electrode tipped catheter into the patient’s vein, typically through a numbed area in the groin or neck. The physician then guides the catheter by hand up to the patient’s heart and cauterizes tissue within the heart’s chambers that is misfiring and causing the irregular heartbeat. The guidance of this catheter is traditionally done through an X-ray or fluoroscopy in order to map the patient’s heart. Then it is up to the skill level of the physician to move the catheter through this moving three-dimensional environment to the right place, find the tissue that needs to be ablated and then destroy the tissue to complete the procedure.

The problem with present day catheter ablation relies in the reliance of the physician and the imaging technology at their disposal to navigate the complexities of the human body. The manual dexterity required by the physician is great and the amount of training to attain it is extensive. Even in the most experienced hands, the reproducibility of arriving at the same anatomic sites in a rapidly beating heart can vary greatly. Due to the nature of the imaging technology, current procedures also expose the patient and the staff to considerable radiation and have been associated with potentially
fatal tissue perforations and other procedure-related complications.

This is where Magnetecs decided to make a difference and revolutionize catheter ablation. Through the use of their advanced CGCI system, Magnetecs has found a way to use electromagnetic fields using robotic control under the direction of a highly skilled EP surgeon to manipulate a specially tipped catheter thru the human body, allowing for precise and consistent site targeting, mapping and ablation efficacy that has never before been possible.

The catheters used for CGCI differ from today’s standard instruments in that the tip is embedded with small permanent magnets that are used to respond to the torque, force and rotation directions being delivered through the eight magnetic fields. The catheter is also made of a softer and more flexible material that is able to be far more pliable and reactive to electromagnetic field control, thereby maximizing movement potential and dexterity through the human body.

The CGCI system is composed of an array of eight electromagnets mounted on a steel frame that the patient’s bed slides into, positioning the frame to surround the torso. The frame provides a focused distribution of the magnetic field within the appropriate heart chamber. Separately, a magnetically protected, integrated X-ray unit is housed within the system’s steel framework to minimize radiation exposure to the patient. Using a joystick interface, the physician is able to utilize a proprietary digital 3D imaging technology that integrates in real-time with the catheter movement to navigate remotely through the human body. This allows the physician to create a custom map of the entire heart as well as the ablation target site(s) that the doctor can manipulate and view in a three-dimensional matrix as well as store all the information in order to review or use again for future procedures as needed. Should the physician encounter a blockage during a future procedure that deviates the catheter from its original path, the mapping can be updated and a new approach saved. As the physician’s commands are now robotically controlled to the CGCI unit, the physician can perform the entire procedure in a separate adjoining suite that eliminates all radiation exposure to him and his operating staff. It is even possible to remotely control the CGCI from any interface enabled CGCI suite in the world via a direct and secure satellite/internet connection.

This ability to accurately memorize, repeat and evolve the process improves successful patient outcomes and additionally increases the speed of the procedure. Time spent training is also reduced and the magnetically guided system allows for greater dexterity with the use of a control interface. Radiation exposure is reduced for the patient and entirely eliminated for the physician, which allows for a savings in radiation shielding costs.

AFib continues to be a growing threat in our society, but with CGCI, cost-effective, consistent and reliable treatment makes dealing with this disease a process that both patient and physician can have high-confidence in.

### 10 Things You May Not Know about AFib

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<th>#</th>
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<td>4</td>
<td>The percentage of all AFib patients who will have a stroke at some point in time.</td>
<td>4. &quot;Atrial Fibrillation (A-Fib) Awareness,&quot; &quot;Atrial Fibrillation Fact Sheet.&quot; Heart Rhythm Society. <a href="http://www.hrsonline.org/News/AtrialFibrillation-AFib-Awareness#axzz29PbYv01H">http://www.hrsonline.org/News/AtrialFibrillation-AFib-Awareness#axzz29PbYv01H</a> Last reviewed: September 07, 2014</td>
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For the next four decades, Bernard continued. He called the procedure cardiac catheterization and advanced it through the aortic valve into the left carotid artery of a horse and attached into the carotid artery of a horse. A glass catheter with a mercury thermometer of the first examples of this was in 1844 when fluids, but that they could serve a role in the active diagnostic and treatment of diseases. At first, catheters were primarily used as a method for draining fluids from the body that were not able to be eliminated through natural processes. This included the first urinary catheters for dealing with blockage from kidney stones or actual kidney failure, to the draining of blood or infectious fluids accumulating in the body or an organ due to internal trauma. Soon however, physicians and scientists discovered that catheters could be used not only as a tool for the passive elimination of fluids, but that they could serve a role in the active diagnostic and treatment of diseases. One of the first examples of this was in 1844 when French physiologist Claude Bernard created a glass catheter with a mercury thermometer attached into the carotid artery of a horse and advanced it through the aortic valve into the left ventricle in order to measure blood temperature. He called the procedure cardiac catheterization and for the next four decades Bernard continued to experiment and advance the catheterization process to measure intracardiac pressures in a variety of animals in order to gain essential insight on the hemodynamics of the cardiovascular system. His work led to the advancement of cardiac catheterization for many different uses by such luminaries as Adolph Fick, Wilhelm Conrad Roentgen and Werner Forssmann.

Catheter Use Today

Today, catheter-based medical procedures range from methods for delivering medications, fluids or gases, to draining accumulated bodily fluids, processes to monitor or “map” internal environments, such as the heart, to treating a variety of life-threatening diseases as in the case of ablation procedures or irregular heartbeat control with the use of Implantable Cardioverter-Defibrillators (ICDs).

In the area of minimally invasive catheter-based treatment of ailments such as Atrial Fibrillation (AFib) it was stated in a paper titled “Trends in Catheter Ablation for Atrial Fibrillation in the United States” by Dr. Patrick P. Kneeland and Dr. Margaret C. Fang, that of the 32 million patients hospitalized in the U.S. for AFib related issues in the year studied, 133,000 required artrial ablation to correct the problem. Further, by correlating all the data from the National Hospital Discharge Survey, it was calculated that since 1990 there has been an approximate 15% increase each year in the number of AFib procedures being performed; and that number continues to rise.

Despite all the advances made through the centuries, the actual core methodology of catheter placement for treatment or diagnosis has remained the same. It is still a thin tube being manually inserted and manipulated by a physician, surgeon or nurse into a patient’s body using their experience and best visualization tools in order to make sure the tip of a catheter ends up where it needs to be and do what it needs to do.

With the significant growth in understanding of the structure and function of the human body that began in the 18th century and with the giant technological leaps in the 19th and 20th centuries in X-ray, fluoroscopy, MRI, CAT, ultrasound orthoscopy and other methods for “seeing” inside a living patient’s body, catheter-based procedures have come a long way from the days of ancient Greeks and Syrians pushing reed and metal tubes into a body simply by feel and best guess trial and error experimentation. With the advent of mass-produced, relatively inexpensive disposable catheters by David S. Sheridan in the 1940’s, catheter-based procedures not only became acceptable, they became safe and cost-effective. Today, catheter procedures for fluid drainage such as Foley Catheterization or Abdominal Abscess drainage are performed thousands of times a day around the world and in the case of the former, the procedure is oftentimes done in-home by the patient themselves.

The truly new frontiers for catheter-based treatment began in 1987 when Dr. James Cox at Barnes-Jewish Hospital developed the Maze Procedure which was the first attempt to ablate cardiac tissue to normalize a patient’s heart rhythm due to AFib. The procedure was successful but as it was done in an “open-heart” environment, it was extremely invasive and risky. Then in the 1990’s catheter-based ablation procedures were pioneered by physicians such as Dr. Michel Haissaguerre and Dr. John Swartz who realized that the pulmonary vein could be used as a transit path to the heart without opening up a patient’s chest. As Atrial Ablation as it came to be known became more and more successful, scientists and physicians began to look to other areas where a catheter-based process might be used to affect diagnosis and treatment.

Currently catheters are used in the treatment and diagnosis of diseases in a wide variety of areas including:

- Administration of intravenous fluids, medication or parenteral nutrition using a peripheral venous catheter.
- Cardio treatments and disease diagnostics such as angioplasty, angiography, balloon septostomy, balloon sinuplasty, cardiac electrophysiology and catheter ablation.
- Femoral arterial and venous catheterization for the direct measurement of blood pressure in an artery or vein.
- Intracranial Pressure (ICP) Monitoring for the direct measurement of pressure in the skull.
- Direct administration of anesthetic medication into the epidural space, the subarachnoid space or around a major nerve bundle such as the brachial plexus.
- The administration of oxygen, volatile anesthetic agents and other breathing gases into the lungs using a tracheal tube.
- The subcutaneous administration of insulin or other medications, with the use of a catheter infusion set and an insulin pump.
• Direct venous delivery for therapeutic drugs or fluids into a large-bore catheter positioned either in a vein near the heart or just inside the atrium.
• The Swan-Ganz catheter which is used for measuring pressures in the heart.
• Embryo transfer to insert fertilized embryos for in vitro fertilization into the uterus.
• An umbilical line used in Neonatal Intensive Care Units (NICU) to provide quick access to the central circulation of premature infants.
• The Quinton catheter which is used in hemodialysis for patient’s suffering kidney failure.
• The insertion of specially “washed” sperm directly into the uterus in artificial insemination.

This is just a short list and it continues to grow every year as new procedures and new types of catheters are developed.

A Limited Technology
Despite all these advancements one thing still has not changed. The placement of a catheter in these advanced procedures still depends upon the dexterity, the experience and the “artistry” of the physician to guide a tube that can range from several inches long to several feet long, through the living, moving, ever-changing three-dimensional environment that is the human body. Magnetecs itself was built on the concept of optimizing a physician’s ability to deliver a catheter on site through the use of magnetic-field guidance and robotic control. With an initial focus on AFib, Magnetecs has proven through more than 100 successful clinical trials that its CGCI technology has the ability to transform the Electrophysiology (EP) field in its ability to map and treat AFib and potentially other cardio-based diseases through the use of a robotically guided catheter.

With the success of CGCI, it was only natural that the Magnetecs research and development team began to look at ways to improve on this newly found technology. They knew that with CGCI they had built a better delivery system, now they focused on building a better vehicle to deliver; the catheter itself.

As early as 2006, Magnetecs knew that one of the limiting factors of its CGCI technology would be the catheter. Prior to CGCI, fluoroscopy and X-ray were the only methods available to allow a physician to see “inside” a patient when attempting to perform a catheter-based procedure. As these imaging methods only produced two-dimensional, low-resolution views of the operation site, success was hyper-dependent upon the skill of the surgeon to achieve a positive outcome. With CGCI it was now possible to create a real-time, three-dimensional map of a patient’s heart that a physician could rotate, turn, and move in and out of in order to precisely “see” not only where they were going, but what needed to be done and what the immediate results were. As much of a breakthrough as CGCI presented, the Magnetecs team realized that even this leap forward could be done better.

MARKET WATCH
Do catheters make business sense?

Catheters have become an indispensable item in the toolset of physicians for the detection, treatment and prevention of a variety of diseases. Nonetheless the use of catheters face growing consumer and medical industry concern over issues of infection and efficacy. As catheters become more as diagnostic and treatment tools, the limitations of a catheter-based procedure are coming into question.

Do these concerns spell the potential demise of the industry or are these issues catalysts and opportunities for visionary business leaders to position themselves for new growth industry within the catheter market?

The Business and Investor Community respond:

November 22, 2010 – Medtronic, a global medical technology company, agreed to buy Ardian, a developer of catheter-based therapies to treat hypertension and related conditions, for $800 million in cash plus a bonus equal to the annual revenue growth through the end of Medtronic’s fiscal year 2015.1

October 8, 2012 – Boston Scientific agrees to buy Rhythmia Medical Inc., a developer of mapping and navigation solutions for use in cardiac catheter ablations and other EP procedures, for up to $265 million.2

November 8, 2012 – Boston Scientific agreed to buy Vessix Vascular, manufacturer of radio-frequency balloon catheter technology, for $175 million and to pay an additional $300 million should the Laguna Hills, CA business meet clinical and sales-based milestones.3

August 19, 2013 – St. Jude Hospital pays $170 million to acquire Endosense SA, a Geneva, Switzerland manufacturer of ablation catheters.4

May 15, 2014 – Boston Scientific buys Bayer’s vascular catheter business for $415 million.5

May 18, 2014 – Spectranetics, a Colorado based medical device company, acquires cardio-catheter maker AngioScore for $530 million to expand into growing addressable markets.6

Josh Shachar turned his mind to the problem and on January 3, 2006 he filed the first of many patents for a new type of catheter technology he called MOSFET. MOSFET stands for Metal-Oxide Semiconductor Field-Effect Transistor and in the patent titled “Apparatus for Magnetically Deployable Catheter with MOSFET Sensor and Method for Mapping and Ablation,” he described a completely new type of catheter that would enhance the ability of the tool to “see” and visualize the dynamics of the living environment it was traveling through and ultimately operating on.

In essence, MOSFET is a vision to bring the existing “black and white low resolution TV antenna” pictures of current imaging methods into the modern day “4K High Definition” world of digital visual imaging we have today.

The problem with current catheter technology’s ability to provide accurate and reliable imaging and data of the area in which it is operating, lies in the inefficiencies of the way in which information is gathered. Modern imaging and ablation catheters today work on the principle of measuring bioelectric potential differences in order to create maps of the area being targeted. Similar to the way a bat uses echo-location to visualize its surroundings by sending out a signal and determining how quickly and strongly that signal comes back, catheters use an electrode tip to measure the “electrical potential” or impedance of a cell, tissue or organ in the body. By measuring the impedance, or the ability for the cell or organ to block an electrical signal, the physician is able to visualize the environment they are looking at. By taking successive readings of a target, a physician is able to determine the shape and density of the area being mapped. The development of this technology provided the basis for minimally invasive cardio-ablation procedures as physicians were for the first time able to visualize non-conductive, or damaged tissue, inside of a heart muscle in order to destroy it and restore proper electrical flow to normalize the patient’s heart rhythm.

The Challenge
Through many advances in this technology beginning in the late 1990’s through today, electrode tipped catheters and corresponding signal translation equipment, which convert the readings into visual maps, have become much more efficient and reliable. Despite this, the technology still has some core underlying problems which have proved to be limiting factors in the accuracy of catheter-based mapping.

The first is the nature of the electrical energy being measured. Unlike the ability to prove electricity is flowing through a plug in your house by sticking a finger in a wall socket and getting a nice 120 volt zap, the bioelectrical energy generated in the human body is of a much lower scale. Whereas household current in the U.S. is usually around 120 volts and in European countries it is 240 volts, in the human body, electric energy is measured in millivolts or one one-thousandths of a volt. Within the human body, that energy typically ranges from zero to a couple hundred millivolts. So problem one is developing sensing technology that is capable of accurately measuring this extremely low voltage and its related impedance or bioelectric potential consistently, accurately and repeatedly as it traverses a target site.

The second problem is the ability to trust the fidelity of the information being gathered. Data points being measured are calculated based on the
difference between the voltage the electrode emits and the resistance of that signal by the cell, tissue or organ it is measuring. Since this voltage is so small, there are many variables that can affect the results that the sensor reads.

First is the ability to insure the voltage being sent to the electrode remains constant. Since current EP electrode catheters use a pre-line amplifier that is located at the physician side of the catheter outside the body to generate the voltage to the electrode tip, there are many factors which can decrease or alter the fidelity of the signal. These include:

- Inconsistent power regulation within the amplifier.
- Degradation of the signal as it travels down the length of the catheter to the electrode due to faulty material, actual distance being covered, and the ability to control and measure the signal being output by the electrode tip.
- Pollution of the signal due to the ambient electrical “noise” of all the surrounding tissue the catheter is moving through can also affect the quality of the signal.
- Quality of the sensing electrode to isolate targeted tissue impedance versus all the other extraneous and ambient noise.

Think of the first time you listened to a heart through a stethoscope. You hear the heart but you also hear air moving in and out of the lungs, digestive fluids processing a last meal and just general internal body noise. Let’s face it, the human body is one noisy machine and it takes an extremely accurate instrument in the hands of an extremely skilled physician to isolate out the sounds that are important from those that are not. The same philosophy applies here.

This presents the second major issue with current electrode mapping technology; the ability to ensure the message received is the same message sent. Remember, this signal path is not a one-way road. Not only must an electrical signal travel cleanly to the electrode tip, it must then be discharged against the tissue being examined, take the resulting reading and send it back down the catheter to the diagnostic equipment for decoding into a language the physician can understand. Since we are dealing with millivolts in a radio frequency analog spectrum, it is easy to see how difficult it is to maintain a consistent, quality reading. It is very much akin to trying to maintain an AM radio station on your car as you travel further and further from the originating tower. We have all experienced this phenomenon: as we get further and further from the transmitting source, that great song we were listening to first begins to get distorted and then fades away as more and more interfering RF waves contaminate the signal. We can always try a bigger antennae but at some point, distance and signal strength will be compromised and finally lost. Add to that what happens when you travel under a bridge or through a tunnel, now the signal is not just getting worse, it gets completely cut off.

Of course, modern technology has come a long way in attempting to lessen and eliminate these inherent problems through better transmitting materials, better isolation around the transmitting line and better algorithms for being able to “tease” out the resulting data to be more accurate and reliable. But as the generation of the signal is being done at the external end of the catheter and the data analysis is being processed after the signal has traveled the length of the catheter and back, it is easy to understand how post-processing algorithms can distort and mask the true nature of the signal and wash out critical clinical details resulting in a less than optimal mapping of the target region or an incomplete picture of the underlying nature of the disease mechanism.

**MOSFET – The Solution**

MOSFET seeks to solve both of these issues and provide a quantum leap forward in catheter-based EP electrode technology.

MOSFET provides an unprecedented approach to solving the major deficiencies in catheter electrode technology by:

- Providing source-point signal amplifier to eliminate signal degradation.
- Providing a sensor array that is much more efficient at distinguishing relevant data from extraneous noise.
- Providing a method for interpreting the resulting data at the sensor point instead of post signal processing as done today.
• Conversion of the analog information to true digital information after processing in order to transmit the signal readings in a high-definition, uncompromised language back to the physician.

To begin with, the Magnetecs’ team has developed a proprietary and patented method for employing a “local” signal amplifier within the electrode tip. By miniaturizing and moving the amplifier from a pre-insertion point to the electrode itself, initial generated signal fidelity is greatly enhanced. Not only is the signal fidelity improved, but corollary problems including Signal to Noise Ratios, limited sampling rates and bandwidth considerations, and the ability to differentiate between near-field and far-field components are all but eliminated.

Next, a data processing engine has been integrated into the electrode so that all signal readings can be correlated and interpreted at the source as soon as they are taken. Again by moving this aspect of the process from the end of the signal path’s journey to the point at which data readings are taken allows for a substantially more accurate interpretation of the data points to be made thereby greatly enhancing the physician’s ability to accurately “see” and map the target site. This also allows a physician to immediately see how effective a treatment protocol has been and to make any adjustments as needed. In the case of Atrial Ablation for example, a physician will know if the tissue that has been ablated has been correctly targeted and achieved the desired results.

Finally, the team is developing an analog to digital converter at the electrode tip in order to change the data results going back to the physician from an RF analog signal (our AM radio) to a high quality digital signal that is able to keep its fidelity intact on the journey back to the physician’s diagnostic display equipment.

The MOSFET technology is being developed to utilize all the advantages of Impedance Spectroscopy, the ability to measure the bioelectric impedance at a cellular level, into a complete and fully integrated processing unit that operates at the target site in order to dramatically improve the visualization and accuracy of catheter-based EP electrode technology. Just as the microscope opened up new windows for physicians to accurately see the previously hidden world that existed at the cellular, atomic and sub-atomic levels, so MOSFET will open new windows for a physician’s ability to study the inherent relationship between the substrate, the tissue

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**Building a Strong IP Portfolio**

Since 2006 Magnetecs has been aggressively consolidating a strong U.S. and Global Intellectual Property Portfolio to make sure the MOSFET technology would be unassailable in the marketplace from any claims of infringement or any other company that might wish to participate in this market utilizing the proprietary innovations that MOSFET provides. Following is a list of the current patents that have been filed. Magnetecs intends to continue to build this portfolio as MOSFET moves into the certification and clinical trial phases.

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<th>Patent Type</th>
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<tr>
<td>W.O. Patent</td>
<td>2007/100,559</td>
<td>02/20/2007</td>
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<tr>
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<td>1,986,560</td>
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<td>U.S. Patent</td>
<td>13/621,727</td>
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or organ being examined, and its electrical activity counterpart at a level of accuracy and detail that has not been possible before.

Validating a New Technology
Since 2006 Magnetecs has filed eight patents in the U.S. and internationally to validate and strengthen its MOSFET IP portfolio. Ongoing research and development as well as benchmark testing have all shown the ability of the MOSFET technology to vastly outperform its current counterpart.

In September of 2012 Magnetecs successfully completed an initial, or pathfinder, MOSFET system that validated the concept of utilizing the localized amplification characteristics of MOSFET technology to increase the sensitivity and accuracy of bioelectric potential measurement.

The study showed a comparison of the local amplifier employing MOSFET versus the remote amplifier with a standard EP electrode catheter was conducted.

Simulated cardiac QRS signals (heartbeat rhythms as you would see on an EKG) were created by a programmable generator and measured along two different signal paths. One employing a post-amplified, current electrode technology, and the second channel utilizing the locally amplified MOSFET sensor technology.

The first signal that was tested was tuned to just under 50 millivolts by adding a series of attenuators to the input signal of a standard electrode catheter which resulted in a total signal gain of 128. This post-amplified signal was sent through the catheter and the return signal was then measured to determine if any signal loss occurred. Not surprisingly, the measured signal was nearly imperceptible at this level due to noise degradation that had occurred along the signal path. In other words, the signal was virtually useless.

In contrast, when the same signal was run through the pre-amplified MOSFET path, it was shown to be well-formed and the cardiac properties, the heartbeat, were clear. Here, the total signal gain was only 100 simply by moving the location of the gain block from one end of the catheter to another.

When the QRS-simulated signal is captured by the local amplifier at the site of the electrodes, linked to a MOSFET sensor, the result is substantially identical to the “pure” standard.

MOSFET Technology Applications
Currently Magnetecs’ has developed catheter models in the following categories:

- Bipolar MOSFET catheter with irrigation
- Quadrupolar MOSFET catheter with irrigation
- 84-electrode basket or balloon MOSFET catheters
- Spiral MOSFET catheter

In addition the team is working on developing a proprietary line of ICD leads for use in regulating cardiac rhythm.

One significant area of note is that MOSFET was not just developed to improve the ability for Magnetecs’ CGCI system, but rather, the MOSFET electrode can be adapted to any of the standard EP catheter systems on the market today which opens a huge market potential for sales.

It is anticipated that MOSFET will be able to significantly capture the EP electrode catheter market for applications including:

- Cardiac mapping and ablation.
- Vital organ mapping for renal, gastrointestinal and even cerebral visualization.
- Renal Denervation for the treatment of hypertension.

“The vision Magnetecs’ has set for itself is only equaled by the innovation it continues to show with each new frontier it conquers.

– Dr. Vivek Reddy
Surgical Cardiologist and Professor at Mount Sinai Hospital

[Image of a doctor]
• ICD leads for the regulation of heart rhythms.

One of the rising potential uses where MOSFET can have tremendous impact is in the area of Neuromodulation. This is a process where direct stimulation of the nervous system, the spinal cord or the brain is done by feeding small electrical signals via an electrode catheter in order to regulate or treat a variety of health issues including:

• Parkinson’s disease
• Essential tremor
• Primary dystonia (sustained muscle contractions cause twisting and repetitive movements or abnormal postures.)
• Chronic intractable pain of trunk and limbs including:
  • Chronic back and leg pain associated with Failed Back Surgery Syndrome
  • Complex Regional Pain Syndrome (CRPS)
• Peripheral vascular disease
• Intractable angina pectoris
• Future uses are seen for treating epilepsy, seizure disorder and forms of dementia.

The Market

The estimated addressable markets for Magnetecs’ MOSFET disposable catheters and additional devices being currently developed are significant and represent sizable opportunities for growth. In the field of Electrophysiology alone, the current addressable EP catheter market for MOSFET technology is estimated to be approximately $3.9 billion. Renal Denervation catheters for treatment of hypertension are estimated by industry analysts to make up a growing market opportunity that will represent $2.5 billion by 2020.

Comparable growth is expected in the market for ICDs and their associated catheter leads. Analysts expect that with over 500,000 implants being done annually around the globe today, this sector will comprise $7.8 billion of the disposable catheter market in 2014.

With benchmark testing completed and a lucrative and expanding market clearly defined, Magnetecs is now ready to begin the process of commercialization. Magnetecs intends to form a wholly owned subsidiary to develop, gain regulatory certification and then market and license the MOSFET technology and all of its core and spin-off product candidates. The company is to be called Magnetecs Catheter Corporation (MCC) and is looking to be incorporated and operational by the end of 2014.

The primary function of the company will be the following:

• Solidify its core management and executive team.
• Begin the process of raising capital to achieve its benchmark timeline.
• Continue the validation of the technological and clinical superiority of the MOSFET biopotential sensor technology.
• Develop, test and certify the first line of MOSFET bipolar EP catheters
• Develop and test diagnostic catheters with the following geometries:
  • Bipolar
  • Quadrapolar
  • Decapolar
  • Spiral

Addressable Markets

The commercialization of MOSFET is perfectly positioned to capture the expanding market for electrode tipped disposable catheters. By offering a level of accuracy, affordability and ease of use, there is no other product technology currently on the market that can compete with it. In the area of Electrophysiology alone, the catheter market is expected to be a $15 billion/year industry by 2020.

Not only will this benefit Magnetecs marketability of CGCI, since the MOSFET technology can be adapted to all current catheter manufacturing standards, the cross-marketing and co-venturing potential of this product is staggering.
• USDA approval to perform:
  • In-vitro study
  • In-vivo animal study
• Clinical human trials at two separate locations
• UL Certification
• CE and CB Certification for marketing in the EU and most non-U.S. markets.
• ISO and IEC Certification
• FDA (501K) Certification for Marketing in the U.S. (pending U.S. acceptance of Renal Denervation protocol.)
• Develop strategic relationships with major catheter manufacturers as well as global medical centers for the sale/licensing of the MOSFET product.

Strategic Partnering
To this last point it is worth looking at just one area where strategic partnering in the form of licensing or joint venture will have a tremendous impact on the growing value of MOSFET technology; Renal Denervation.

Renal Denervation catheters as stated above are estimated by industry analysts to represent a market opportunity of $2.5 billion by the year 2020. Renal Denervation is a minimally invasive catheter-based procedure for patients with pharmaceutical- and lifestyle-based-resistant hypertension. Studies indicate that approximately 120 million people are affected by this form of hypertension worldwide. In a Renal Denervation procedure, a catheter is placed in the renal artery, which supplies blood to the kidneys, to deliver controlled, low-power radio-frequency energy to deactivate surrounding nerves. The procedure modulates the output of the nerves that lie within the renal artery wall and lead into and out of the kidneys. These nerves are part of the sympathetic nervous system that regulate blood pressure affecting major organs including the kidneys, the brain and the heart. Renal Denervation devices have been shown to selectively modulate the sympathetic nervous system affecting hypertension and minimizing the systemic adverse effects of hypertension drugs.

Although Renal Denervation is a medical specialty in an embryonic stage of development, major medical companies are already recognizing and investing into the growth potential of this treatment area. Medtronic, Inc. (NYSE: MDT), the world’s largest independent medical technology company, has realized the potential of the Renal Denervation market at an early stage and has invested $47 million to acquire 11% of Ardian, Inc. in March of 2009. Ardian has developed the Symplicity™ Renal Denervation system for patients with treatment-resistant hypertension. At the time of this investment, Ardian had completed animal studies and a 45-patient first-in-man clinical trial. The Symplicity Renal Denervation system was launched in April of 2010 following CE Mark approval.

In addition, Covidien Ltd. (NYSE: COV) acquired Maya Medical, developer of the OneShot Renal Denervation system, in April of 2012. St. Jude Medical (NYSE: STJ) has developed its EnligHTN Renal Denervation system in-house. There are currently a total of four new Renal Denervation systems available in Europe and other markets outside of the U.S as the FDA has not yet approved a Renal Denervation system. However, the Medtronic Symplicity system has received an Investigational Device Exemption for studies and could receive FDA certification in 2014. In September of 2012 Medtronic announced results of a health-economic analysis suggesting that Symplicity is a cost-effective procedure that may reduce cardiovascular morbidity and mortality for patients with treatment resistant hypertension. Medtronic executives have been noted in a securities industry report to acknowledge that Symplicity represents early-stage technology that will require enhancement to retain a competitive advantage.

The Future
All of this points to a staggeringly large and expanding demand for sophisticated and effective products that will be able to meet and address this growing need. The MOSFET technology is not only the solution for Magnetecs’ ability to be at the forefront for use in its CGCI platform, but it provides the entire medical device community and the physicians they serve, a ground-breaking tool to their disease detection, prevention and treatment arsenal. More importantly, MOSFET provides the patients whose lives this technology can affect, a major leap forward to improved success rates and prolonged life.
Our heart is an amazing organ. It is the engine that drives all life forces in our body. During an average lifespan it will beat 2.5 billion times oxygenating and moving more than 50 million gallons of life-giving blood through our body. It is the motor that carries all the nutrients from the food we eat, all the disease-fighting blood cells to keep us healthy, all the oxygen from our lungs into our cells, and helps remove much of the toxins and waste products from our system. It is arguably the most important organ in our bodies and the one in which the modern age and our lifestyle choices have put at incredible risk.
Our Hearts Under Attack
Heart disease is the leading cause of death both in the U.S. and around the world. The Center for Disease Control (CDC) estimates that about 600,000 people die every year in the U.S. That is about a one in four chance of dying from a heart-disease related issue. The statistics are not that much better when expanded to a global viewpoint. It is estimated that in 2012, 17.5 million people died from heart-disease. That equates to three in every ten deaths were related to a heart failure condition. The growing epidemic follows a concerning trend in obesity, diabetes, poor diet and lack of exercise – a trend that is reaching across generations at this point and creating a debilitating family history that only serves to increase your risks.

These types of coronary disease typically involve plaque buildup in the arteries, which could lead to potentially life-threatening heart attacks or strokes. Heart attacks occur when these clots restrict or block blood flow to the heart whereas strokes are caused by impedance of blood flow to the brain. Someone in the U.S. has a heart attack every 34 seconds and a stroke occurs every 40 seconds. Some examples of heart diseases that could trigger these catastrophic events include AFib, cardiomyopathy, high blood pressure, peripheral artery disease (PAD) and many more.

Although current treatments vary depending upon the type and severity of heart disease, the main focus of treatment tends to rely on prevention or mitigating the damage done so as to go on living with the condition. These methods include:

- Lifestyle Changes such as:
  - a healthy diet,
  - moderate exercise on a daily basis,
  - reduction of stress and anxiety levels,
  - maintaining a healthy weight, and
  - elimination of smoking and excessive drinking.
- Medicines such as:
  - blood thinners,
  - beta blockers,
  - cholesterol reducers, and
  - anti-arrhythmic drugs.
- Procedures and Surgeries such as:
  - angioplasty,
  - bypass,
  - catheter ablation, and
  - pacemakers.

While slowing the progression of any disease is a success, advanced research into rejuvenating or creating healthy heart tissue takes treatment to the next level and has the potential to improve the quality of life substantially.

Stemming the Risk of Heart Failure
One of the rapidly growing areas of interest for the ability to naturally rejuvenate the heart lies in the arena of stem cell research. Stem cells are the body’s undifferentiated cells that have the potential to adapt into other cell types thereby repairing and renewing organs and tissues. Stem cells are the naturally occurring cells upon which our entire body is built. From the moment of conception, the first cells that are created in the blastula, the sphere in which a fertilized ovum develops, are simple stem cells. As the embryo evolves, these stem cells begin to differentiate into heart cells, liver cells, brain cells and so on; and this process does not end in the embryo. Once we are born, our body continues to produce stem cells, now called adult stem cells as opposed to in-utero embryonic stem cells. Mostly concentrated in our bone marrow, but also present elsewhere in our body, adult stem cells continue to produce throughout our lives as natural regenerators for diseased tissue. Though the mechanism for how this works is well understood, the ability for adult stem cells to be produced and called on demand to replace unhealthy cells and tissues is still an area of research that is a ways off in producing reliable results.

What is known is that adult stem cells are constantly aiding and renewing the human body from normal wear and tear, which is why continued research into harnessing the basic functions of both embryonic and adult stem cells on a greater scale is so important.

The ability for embryonic stem cells to be artificially introduced into a section of diseased tissue and then to begin their natural process of replacing those cells by differentiating, or transforming themselves into cells of that type, is a well-researched and documented process. However social and moral concerns have made the research into and the utilization of embryonic stem cells a political hot-potato that has hindered the
“evolution” of stem cells as a therapy and disease treatment protocol; especially in the U.S.

Understanding Stem Cells
The main objection in the use of human embryonic stem cells lies in the fact that the only way to harvest these cells is from extraction of the pre-implanted human embryo or blastocyst upon isolation of the inner cell mass that holds the undifferentiated stem cells. Further research is taking place into maintaining the embryo by removing a single stem cell that would then be multiplied in vitro. Regulatory forces currently in place require the consent and authorization of human egg and sperm donors for use in embryonic stem cell research.

Putting aside moral quandaries, both types of stem cells have advantages and disadvantages. Embryonic stem cells are pluripotent and can become any cell type in the human body while the adult stem cell is limited to the type of tissue it was taken from. Embryonic stem cells are fairly easy to culture in labs, while the isolation of adult stem cells can be difficult depending on the maturity of the tissue sample. Since the success of stem cell therapy in part lies in the vast numbers of cells needed to be effective for a specific treatment, being able to cultivate a greater amount of the cell-type needed is integral to the process.

From this standpoint, the ability to more efficiently cultivate embryonic stem cells seems like a better candidate for stem cell therapy procedures. It’s important to recognize however that every form of cell, organ or tissue replacement therapy relies on the body’s acceptance of treatment. Like a transplant, a foreign element, in this case embryonic stem cells, have the potential to be rejected by the host immune system. Adult stem cells do not have this problem but science is a long way off from being able to harness the ability to harvest, cultivate or generate adult stem cells to a degree where they can be used for effective treatment.

As mentioned previously, embryonic stem cells are pluripotent or can become any type of cell – an ability that is extremely desirable when you note that there are over 200 different adult cell types in the human body. Research is currently being conducted on induced pluripotent stem cells, which are basically adult stem cells that have been hacked and reprogrammed back to a state similar to embryonic stem cell state allowing them to differentiate unbiased.
Another form of stem cells are hematopoietic stem cells, which have been widely accepted and used for years to treat blood disorders including forms of cancer that target blood cells. These stem cells can be extracted from bone marrow and umbilical cord blood and are responsible for the continual renewal and immune boosting of blood cells. Unfortunately, these types of cells cannot replicate and differentiate in a laboratory culture thus limiting their potential for the time being. In the meantime, they show great potential in cardiomyocyte or heart tissue regeneration.

So the focus remains on embryonic stem cells as the more promising path to take. The challenge then becomes, how to minimize the chance of rejection of the embryonic stem cells into a host site, and how to deliver them on target exactly where they are needed.

As far as rejection goes, the standard medical protocol remains the same as for any organ or tissue transplant; through the use of immune suppressing drugs that can slow the body’s natural tendency to fight off the “foreign” agent giving it a chance to adapt to the new host environment. However, this opens the patient up to the chance for microscopic disease in the environment or with the injected cells to created secondary infections. In theory, if adult stem cells could be harvested and cultivated from the same patient, then rejection becomes a far smaller issue allowing for a greater acceptance rate and decreased use of additional medications.

**Delivering a Solution**

This localized delivery of stem cells is critical to successful treatment as releasing them en mass systemically, through an injection or IV mechanism, does not ensure that the cells will arrive where they are needed in a sufficient quantity to affect a cure. In addition, as embryonic stem cells have the ability to differentiate into ANY cell type in the body, it is possible for them to become harmful cells, such as a cancer cell or an immune-compromised cell. Delivery of the cells through an open-body surgical procedure leaves the patient open to all the associated risks including infection, reaction to anesthesia, secondary complications and more. Getting the stems cells to a damaged area in a concentrated dose while sustaining a closed environment reduces the risk of harmful cell replication and invasive surgery. This strive for accurate manipulation and consistency is why this type of research takes a long time, vast resources and strict regulations.

By utilizing targeted guidance systems to disperse the precursor stem cells directly to a target site, say a section of a coronary muscle damaged by heart disease, will greatly improve the ability for those cells to repair damaged cells and even replicate into healthy tissue that revitalizes the organ. By utilizing the body’s own repair system on a greater scale, the chances for successful implementation are greater.

In the past decade, several large companies and billions of dollars have been tasked to the research and development of an effective way to address the growing problem of heart disease through stem cell therapy. Initial results have proven very promising and in the EU, stem cell therapy for heart disease is already an approved and growing procedure.

**The Magnetecs Opportunity**

Magnetecs is now looking into a method by which its CGCI system might be used as the transport device for this promising form of therapy, especially in the field of heart failure. Heart failure kills hundreds of thousands of people a year, and to date the only proven treatment is heart transplantation. Tragically many patients do not survive the wait time for a replacement heart, or succumb due to rejection of the new organ.

As the acceptability and demand for stem cell-based procedures for heart failure grows, Magnetecs feels a joint-venture with a leading and established pioneer in this area would create an opportunity for both proven, high-value Intellectual Property companies to deliver a solution to the marketplace that will turn this killer disease into a chronic, managed disease.

The envisioned joint-venture that could arise between the parties will see them contribute unique expertise to create a novel, high value, clinically significant entity which can transform lives and deliver significant shareholder returns.

“Electrophysiology is all about knowing where to go, how to get there and what to do.

At the core of Magnetecs transformational technology is the ability to provide the physician the best road map, delivery system and support to bring about the best possible outcomes for their patients.”

— Dr. Asher Holzer
Paving the Road to Success – Prof. Petr Neuzil, MD, PhD

The process of bringing a medical device for human use to market, is an arduous path. Event the most needed, simple medical technologies face years of rigorous testing, study, clinical review, certification, and regulatory oversight before it can begin to see a path to commercialization. The cost in time, man-power, and money can be staggering and only those who are truly committed to their vision or have access to unlimited funding succeed. This is why it is critical that any company hoping to be successful in the advanced technology medical device marketplace develop strategic relationships with those that have gone before who know how to navigate the waters of regulatory and clinical study in order to help fast-track as quickly as possible a much needed technology into the marketplace where it can begin to save lives.

Magnetecs is fortunate to have just such a person in Prof. Petr Neuzil, MD, PhD. Dr. Neuzil is head of Cardiology and Director of the Cardiac Arrhythmia Service at Na Homolce Hospital in Prague, in the Czech Republic. He is a well respected authority on heart disease and especially in the area of Electrophysiology. He is an author and co-author of many scientific papers on the topic and is often asked to speak at global cardio-symposiums as well as general medical conferences on his work and theories.

Dr. Neuzil recently participated in a global study of the Stereotaxis Robotic Ablation System. The study was conducted at four of the world’s most prominent arrhythmia treatment centers, including, Hospital of the University of Pennsylvania, Indiana University School of Medicine, Na Homolce Hospital, and University of Leipzig. In the study fifty-three patients with previous severe heart disease were treated with ventricular tachycardia (VT) with the Stereotaxis system. The acute success rate in the study was an impressive 94 percent, and no patients suffered a major complication. The acute success results obtained from the STOP-VT study are 10-15 percent higher than similar published studies using conventional ablation techniques.

As a result of the study, Dr. Neuzil became very excited about the future of EP using robotically controlled catheter guidance systems for treating heart diseases such as AFib and VT. As such, he has accepted the task of being the Lead Investigator for the Clinical Trial studies for CGCI’s new EP suite located Na Homolce. Working closely with Dr. Vivek Reddy and Dr. Eli Gang, this team will be responsible for ensuring the fidelity of the studies now being undertaken as well as the safety of the patients and all involved in the program. With Dr. Neuzil’s expertise in the science, the local and regional medical community and his strong affiliations to oversight agencies and the regulatory boards, we at Magnetecs feel we will be able to quickly gain validation and acceptance of our CGCI technology in the Eastern European region.

Magnetecs has a unique, proven and approved technology to identify and map the shape and size of the heart muscle scar which causes heart failure as well as the ability to deliver stem cell drugs to the scar tissue. Furthermore, as Magnetecs’ CGCI suite is installed in several countries already and has CE mark approval, the ability to enter this market, to map and inject heart muscle stem cells through a minimally invasive catheter, is a unique combination, without comparison and offering near-unassailable barriers to competition.

The new venture will advance the technologies and IP of both companies while bringing to market a drug/device combination that could literally save the lives of thousands of patients. The resulting expansion of our already significant addressable market, also will ensure significantly increased value and return to both companies.

The field of regenerative stem cell therapy is extremely exciting and holds immense potential for the treatment of heart disease. The potential for expansion into cures for issues such as Parkinson’s, spinal cord injuries, diabetes and other diseases is enormous. Using CGCI as the delivery vehicle for making sure the cure can get to where it can be most beneficial, opens the door to new possibilities that are endless in scope, immense in return and boundless in the ability to bring new hope to millions of patients around the world.

“Magnetecs has created a differentiated Medical Robotic navigation technology for non-invasive procedures. The company is uniquely positioned now to leverage this technology by forming partnerships and collaboration with world class drug and device players and create significant value.”

– Eytan J. Lombroso
It has been said that the definition of a leader is defined by three actions. The first is to define a glorious vision. The last is to say thank you and in between, the leader is simply a servant and inspiration to the work of his team.

Dr. Abay is just such a leader. An accomplished Neuro-Surgeon and philanthropist who brings years of medical knowledge and business expertise to Magnetecs, Dr. Abay has proven time and time again that he has the stature for others to follow and the humbleness to let others lead. We are fortunate to have an expert on building an extremely successful multi million-dollar business, which has become a model of healthcare. His forward thinking, international alliances, business, medical and scientific background create a key component for Magnetecs intended Global Expansion. Dr. Abay’s impact on Magnetecs has already opened doors wider towards our goals of becoming even more of a significant positive force in cardiac health care internationally.

Dr. Eustaquito O. Abay II

He has successfully founded and built one of the most prestigious spinal hospitals in the United States, The Kansas Spine Hospital, located in Wichita, KS, is one of the nation’s only fully digital hospitals. The vision of founder Eustaquito Abay, M.D., it was of the first hospitals to digitize patients’ medical records, from prescriptions and clinical records to X-rays and other radiology images, and make them accessible by computer. To move to a VoIP business communication solution, the hospital turned to Authorized Toshiba Dealer Great Plains Communications, also of Wichita.

Dr. Abay was also among the founders of the Mayflower Clinic, a charitable clinic that was started in 2010 by immigrant physicians in Wichita. He served as a Clinical Assistant Professor of Neurosurgery at the University of Kansas School of Medicine-Wichita and was an appointed member of the Kansas Board of Healing Arts.

Published journals, books, chapters and lectures by Dr. Abay add additional concrete to the foundation of a legacy dedicated to helping others.

Listed as one of the top 10 influential people in healthcare of the Wichita Business Journal Magazine he has shown his dedication to medicine and his fellow man by traveling overseas to unselfishly offer his services, time and resources to people in need of quality healthcare.

Dr. Abay’s ability to create, communicate and deliver is an invaluable enhancement to Magnetecs.

Energy

Education

• Mayo School of Graduate Medical Education Residency, Neurological Surgery
• Mayo Graduate School of Medicine, University of Minnesota Other Training, MSc, Neurosurgery
• University of Pennsylvania Internship, Transitional Year
• University of Santo Tomas Medical School
• Ateneo de Manila University Other Training, BA, Departmental Honors in Biology

Professional Memberships

• American Association of Neurological Surgeons – AANS Fellow
• American College of Surgeons – ACS Fellow
• American Medical Association – AMA Member
Josh Shachar is an inventor and a mathematician with more than 20 years of experience in the fields of advanced medical technologies and military systems. He holds 160 active patents and applications and is the principal owner and founder of two military aerospace companies, Engineered Magnetics, Inc. and EDEL Engineering Development Corp., both of which have been developing proprietary advanced defense technologies for the Department of Defense (DOD) for more than twenty years. Josh is also the co-founder and CIO of Pharmaco-Kinesis Corporation, the parent company of a series of high-technology smart medical device companies.

Josh served in the Israel Defense Force before beginning his studies at the Sorbonne University in Paris and at Haifa University in Israel where he graduated magna cum laude with a Bachelors and a Masters degrees in the philosophy of science and mathematics. He then came to the U.S. on a Fulbright Scholarship to continue his studies at USC.

Upon leaving USC, Josh founded and held executive positions in a series of technology firms where he was a key figure in the engineering and innovation of many advanced technologies that are still in use today and lie at the core of our nation’s defense systems.

In 1996, Josh turned his attention from military defense work to medical technology and secured the first patent for the guidance of a catheter through the human body using magnetic force. This ultimately led to the founding and growth of Magnetecs Corporation and the creation of CGCI, the world’s first robotic assisted catheter guidance system.

Eytan is a leader in business development with an acumen for keen strategic insights and aggressive business growth strategies for companies that have a solid foundational market offering. For over 30 years he has held leadership positions in the investment and commercial banking industries as well as healthcare and advanced technology companies.

Eytan studied at Massachusetts Institute of Technology as part of the Advanced Executive Graduate Program. He also holds an MBA from Pepperdine University in Los Angeles, and a BS in Industrial Engineering and Management from the Technion - Israel Institute of Technology.

Eytan served for 14 years as Senior executive at JP Morgan Chase, where he built several high performing businesses and commercialized technology. He was responsible for developing internet related strategies and investments for all retail bank businesses, building new E-Commerce and International Card entities in Asia and Latin America. Eytan also led the restructuring and profitability enhancement of Chase Merchant Services and managed the Retail bank merger between Chemical Bank and Chase. Eytan also served as the Senior Managing Director with Allegiance Capital, a mid-market investment bank with responsibilities for managing the East Coast and Israel offices, where he focused on advisory consultation, mergers and acquisitions as well as corporate finance activities. He also served as a Senior Consultant for Coopers & Lybrand, a management consulting practice in New York.

In 2003 he became one of the co-founders of Magnetecs Corporation along with Josh Shachar, Frank Adell and Dr. Eli Gang. In 2009 he founded a biotech company called Neonc Technologies.
Eli is a respected and highly recognized diagnostician, surgeon and authority in the field of Cardiovascular Medicine and Electrophysiology. He is a Clinical Electrophysiologist and is Board Certified in Internal Medicine, Cardiology and Clinical Electrophysiology. He has been a physician for over four decades with thousands of successful patient outcomes, and has published over 100 papers and articles in dozens of peer reviewed publications. He is highly skilled in the diagnosis and treatment of complex arrhythmias, and is an expert in radio frequency ablation and the implementation of pacemakers and automatic defibrillators.

Eli obtained his BA from Columbia College in New York City and then went on to receive his MD from Columbia University’s College of Physicians & Surgeons. Eli taught Clinical Electrophysiology at the famous Tel Hashomer Hospital in Israel in 1982 before taking the position of Co-Director of the Clinical Electrophysiology Laboratory at Cedars-Sinai Medical Center in Los Angeles from 1983 to 1988.

Currently, Eli is a Clinical Professor of Medicine at the UCLA Medical School and General Partner at the Cardiovascular Medical Group of Southern California. In addition, he is a Fellow of the Heart Rhythm Society, the American College of Cardiology and the American Heart Association.

In 2011, U.S. News & World Report ranked Eli as one of America’s Top Doctors according to a peer survey conducted.

In addition to being one of the co-founders of Magnetecs, he has established strategic relationships between the company and medical community. He has also authored several papers to enforce the potential for CGCI including “Dynamically Shaped Magnetic Fields: Initial Animal Validation of a New Remote Electrophysiology Catheter Guidance and Control System” which was published by the American Heart Association in the medical journal Circulation: Arrhythmia and Electrophysiology.

Frank is an executive with over 20 years experience in strategic planning and marketing development for several successful technology startup companies. He is experienced in developing marketing strategies designed for raising investor funds as well as negotiating strategic alliances programs. He has recruited high senior management teams and governing boards for many Fortune 500 clients such as GE, Intel, Pfizer, Merck and Bristol-Myer-Squibb. He also has developed extensive working relationships with the venture capital community.

Frank began his professional career in 1980 as a nuclear engineer at Bechtel Corporation after receiving his BS in Nuclear Engineering from the University of Washington in Seattle. In 1985 he founded Newzaust, Inc., an International Marketing Consulting Firm that specializes in introducing innovative technology systems to Fortune 500 companies in the U.S.

Frank has also worked with numerous government agencies, including the State Department and the U.S. Federal Aviation Administration (FAA). In 1996, Frank received a letter of recognition from the FAA on behalf of former President Bill Clinton for his contributions to the security of the airline industry. He is the recipient of the 2007 Congressional Order of Merit and a member of the Business Advisory Board of the National Republican Congressional Committee. Frank also received the Congressional Medal of Distinction from former President George W. Bush in 2008.
Asher is an entrepreneur and leader with 28 years of experience in the medical device industry and is recognized for transitioning emerging technologies from concept research to clinical standard of care. He brings his experience to Magnetecs in the management of application and product IP as it relates to regulatory compliance. He has extensive experience in business development for both private and public sector corporations in the medical device industry and has substantially contributed to the positive market positioning of Magnetecs.

Asher has been involved in a wide range of activities with regards to the management of advanced medical technologies, including product development, clinical studies, regulatory affairs and marketing. He served from 2005 to 2012 as the founder, President, Chairman and Director of InspireMD, a medical device company which improves treatment of patients who undergo stenting related to heart attacks. Prior to that, Asher served as International Operations Manager for Biosense Carto System, a leader in medical sensor technology. Biosense developed and marketed a novel guided imaging system for craniological and electrophysiological applications which has become the worldwide market leader in cardiological applications. He has developed and commercialized various catheters in the electrophysiology and cardiology fields as well as a vast experience in low noise amplification devices.

Asher received a PhD in Applied Physics from Hebrew University in Jerusalem, Israel where he also received a MS in Material Science and BS in Mathematics, Physics and Computer Science.

Asher also holds several patents, both granted and pending, in the fields of interventional cardiology and urology.

Geoffrey is an Economist with over 50 years experience in the public sector with a focus on real estate ventures. His career includes positions with Lockheed Aircraft International, Northrop and System Development Corp. as well as serving as Senior Economist with Ralph M. Parsons Company. He served as the CA Energy Commissioner from 1982 to 1986, saving Californian’s $10 billion in electricity costs. He later went on to be the founder and co-owner of the Las Vegas Title & Escrow Company and served as the President of the Los Angeles County Probate Referee Association from 1992 to 1993.

He has also been deeply involved with the city of Pasadena and has held such prominent roles as Economic Development Manager for the Chamber of Commerce, the Executive Director and founder of the city’s Development Corporation, Chairman of the Utility Commission, originator of the historic Old Pasadena district and member of the Tournament of the Roses Association for more than 30 years.

Geoffrey currently serves as the CA Probate Referee for the Pasadena and Pomona courts since 1987 and General Counsel of International Power Distributor Inc. of U.S.A. since 2007. He has completed more than 4,000 commercial and residential appraisals in the San Gabriel and San Fernando Valleys and is the managing partner of 25 real estate properties. He is currently the President of the investment partnership firm, Phoenix.

He received his BA in Economics from Stanford in 1959 and attended the J.S.D. program offered by Yale Law School in 1962. After passing the CA bar exam in 1965, Geoffrey obtained his PhD in Program Business Economics from UCLA’s Anderson Graduate School of Business Administration.
Len Epstein
Director

Len has over 40 years of experience in corporate sales and management with an emphasis on creating focused strategies to anticipate market trends. During his business career, he has been active in various industry associations, serving as committee chairman, president, treasurer and board member.

He was founder and President of NorLen Food Marketing Company, a leading food broker in New York City. Starting as a one man operation specializing in dairy products, Len quickly grew the business into the largest food brokerage company in metro New York that expanded into refrigerated food products through the merging of two companies. Employing over 100 individuals, NorLen was well positioned to attract the largest multinational manufactures, some of whose national sales exceeded $1 billion.

After NorLen was sold to another major New York metro food brokerage company, Len went on to Empire Foods where he capitalized on controlling the sales as well as making additional profits through direct importation instead of working as a commission agent. This was accomplished by strength of character, years of industry experience and trade contracts from which solid international strategic alliances were built. By meeting sales volume objectives and government quota systems, Len was able to take Empire Foods from the representative of foreign foods companies looking to sell in the U.S. to a major U.S. importer of branded products.

Len attended Syracuse University and graduated from their School of Management with a BS degree.
As CEO and CTO for Magnetecs, Josh is responsible not only for setting and ensuring the vision for Magnetecs is carried forward, he is also responsible for overseeing the development of all core technologies that the company decides to bring to market. With over two decades of experience in the formation and growth of ten high technology companies as well as being the innovator of hundreds of pioneering products lines including CGCI and MOSFET for Magnetecs, Josh has the unique capacity to see the direction of the markets in which Magnetecs is involved and to meet the demands from both a solution-provider standpoint as well as providing the leadership and vision required to bring those solutions from the drawing board to commercialization.

Josh is also responsible for maintaining awareness of both the external and internal competitive landscape, opportunities for expansion, customers, markets, new industry developments and standards as well as effectively communicate these to the Board of Directors in order for the Board to make sure they remain on-track to meeting the projections and benchmarks established for Magnetecs and its shareholders.

For further background information see Josh’s Board of Directors description in the previous section.

As CMO for Magnetecs, Dr. Gang is responsible for designing animal and clinical trials for current and pipeline products. He also participates in the writing of intellectual property patents, maintaining the integrity of all medical and surgical protocols required in both the development of Magnetecs’ product technologies as well as overseeing all regulatory standards involved in in-vivo and in-vitro testing and any clinical trials the company engages in for the validation and commercialization of Magnetecs’ products.

Eli also represents Magnetecs in any interactions with the medical community. This includes the strategic planning for any installations of the CGCI, working with medical administrators in establishing safety and usage protocols, and supervising multi-site trials and studies as well as presenting Magnetecs’ clinical and basic research results and data at various national and international forums.

In addition, Dr. Gang provides the Board of Directors the medical expertise and information they need to make sure the health and safety of patients participating in CGCI studies or procedures are being kept to the highest standards possible and that the training of the CGCI site installation staff is of the highest caliber.

States Dr. Gang, “Clinical Electrophysiology has seen tremendous growth in the number of patients effectively treated for various cardiac rhythm disorders over the past decade. Nonetheless, many patients remain untreated throughout the world, and as the population in this country ages, the number of patients with rhythm disturbances is rapidly rising. We hope to offer more effective and efficient therapies for these patients using Magnetecs’ novel technologies.”

For further background information see Dr. Gang’s Board of Directors description in the previous section.
Eytan’s three decades of experience in helping to build and operate multi-national companies with a focus on finance and banking, gives him a keen edge in managing the strategic operations for Magnetecs.

As COO, Eytan is responsible for putting into action the plans and vision of the CEO as authorized by the Board of Directors. This includes making sure all aspects of operations from technology development, manufacture, sales, marketing and communications are efficiently staffed and have the means and ability to accomplish the benchmarks established by the executive team. In addition, Eytan is responsible for ensuring the goals and vision of the company are practical and achievable from an operations and budgetary standpoint in order to maintain fiscal solvency and continued growth for the company.

Eytan also plays a key role in developing and maintaining strategic relationships with vendors, customers and affinity partners.

For further background information see Eytan’s Board of Directors description in the previous section.

As CGCI and MOSFET represents a quantum step forward in medical device technology, it is breaking new ground in this highly specialized but competitive marketplace. As such the path to commercialization for these devices comes under much sharper scrutiny than a simple drug reformulation or the creation of a better stethoscope. As such, Magnetecs has brought Asher on board to oversee that the pathway to market is as short as it can be while making sure every safety and regulatory concern is met at the highest standard possible.

In addition, Asher assists in working with the technology team to make sure all practical mechanical and scientific innovation has been thoroughly thought through and is properly documented for regulatory purposes as well as building the company’s IP portfolio.

Asher’s specific experience and reputation in the field of Cardiology is also critical to helping to open acceptance and validation of CGCI and MOSFET to the international medical community.

For further background information see Asher’s Board of Directors description in the previous section.
Christopher has more than 20 years of experience in corporate finance and accounting including responsibility over inventory control, audit coordination and management of individuals involved in all aspects of the accounting function including tax, staff accountants, payables, receivables and inventory. He has held such prestigious positions as Director of Financial Planning and Control, Director of Business Planning and Divisional Controller.

His previous experience includes 16 years with Shiseido, a multinational manufacturer and distributor of prestige consumer cosmetics. While there he was responsible for all aspects of budgeting, treasury and consolidated financial reporting and coordination with all subsidiaries in North America and Brazil as well as developing strategic budgets with the sales and marketing division heads. He is currently on the board of Ballester Hermanos, one of the largest local importers and distributors of frozen and dry goods, beverages and food service in Puerto Rico.

Christopher received his undergraduate BS degree at Lehigh University with a concentration in Accounting followed by an MBA in Finance at Fairleigh Dickinson University.

David has over a quarter century of engineering experience in biomedical, electrical, software and embedded systems. His knowledge extends to all aspects of taking technology innovation from theory to algorithms to final product. He has overseen product management across several stages including research and development, object oriented design, system architecture and implementation, and commercialization.

David began as a Software Engineer for Western Technologies where he wrote a nationally marketed video game for Atari’s 400, 800 and 5200 platforms. Following that he went on to lend his skills in animation and motion capture rigging, editing and processing for video games such as “Exotic Warriors”. He has also been the owner and developer of a Midi sequencing software used for a wide variety of electronic musical instruments.

In later years, David lent his software engineering skills to Yummy Media for the design of custom 3D engines and desktop applications as well as to Neuric Technologies for facial animation in their temperament-based AI system. This experience in 3D and robotics fit perfectly with the engineering and interface design for Magnetecs’ CGCI system.

David earned two BS degrees from Florida Institute of Technology: one in Electrical Engineering and the other in Computer Engineering. He later went on to graduate from the Senior Executive Business Program from Columbia University’s Graduate School of Business.
Paladin is the current Project Coordinator at Magnetecs. He received two BA degrees in History of Europe and Political Science Theory from University of California, San Diego then his JD at Loyola Law School in Los Angeles before moving into the business world. Paladin has also studied accounting, computer science, web design and finance through formal classroom environments and self-education.

Paladin joined Josh’s group in October of 2009, initially focusing on intellectual property development and technical writing while embedded with Pharmaco-Kinesis’ engineering team, work which led to being a named inventor on U.S. Patent No. 8,571,805 (issued October 29, 2013).

He later joined Magnetecs, where he supported the quality and regulatory efforts leading to CGCI’s CE Mark approval in December of 2011. Paladin also provided customer technical support to installation centers, both remotely and through on-site service and training.

His recent work with Magnetecs includes maintenance of the Quality Management System leading to a successful surveillance audit in June of 2014 to maintain ISO 13485 certification. He has also acted as project coordination, purchaser and shipping tester for CGCI’s latest installation in Prague, Czech Republic.

Robert Beck is an expert in software databases, development, validation and testing techniques as well as I.T. regulatory. He has been successful in securing FDA and EU approval for various medical devices in which functionality requires custom software.

He is a Principal Consultant for Software Regulatory, LLC and Methodize, Inc, both of which specialize in obtaining regulatory approvals for medical devices. Prior to Software Regulatory, Robert held the positions of Vice President of Operations at Acclaim Data Analytics and Director of Information Technology and Clinical Data Management at Acorn Cardiovascular. Robert focuses on providing leadership for startup companies struggling with software development in a regulated environment, including ISO 62304, ISO 14971, applicable FDA regulations and Guidance, and the MDD.

He has administered and understands software validation, Part 11 compliance, Quality System Regulations and ISO standards as they apply to software and applicable FDA guidance documents. Robert wrote software sections of regulatory submissions [510(k)s, Technical Files] for a number of successful products, including firmware, software-only and multiple equipment interfaces. He has worked on more than 50 medical devices while in clinical trial.

Robert holds BS degrees in Pharmacy and Microbiology from the University of Minnesota, and certifications as an ASQ Certified Software Quality Engineer (CSQE) and ISTQB Certified Software Tester (CTFL).
Daniel is a meticulous business executive with extensive experience in Federal regulatory compliance, risk, safety & quality assurance management, finance, research & development, marketing, and PR for numerous industries. He has demonstrated success formulating and executing strategic business initiatives to completion, including complex research projects and process improvement plans with a strong record of exceeding corporate profitability goals.

Daniel has participated as a Policy Fellow for the Society of Brain Mapping and Therapeutics (SBMT) which worked on the G20 World Brain Mapping and Therapeutics Initiative relating to the major impact of the cost of neurological disorders on the world economy. He also has experience in positioning the largest nonprofit, private medical center in Western U.S. to earn numerous contracts from leading pharmaceutical and device manufacturers (St. Judes, Medtronic, Stryker, Karl Storz, Magnetecs, Given Imaging). He represented and greatly expanded CA’s Public Health Law to thousands of individuals, encompassing the largest geographic area in the state.

Along with being a community leader and philanthropist to numerous charities, Daniel as also been a keynote speaker and advisor for the CA Institute for Regenerative Medicine (CIRM), the CA Project to Cure Blindness through USC’s Doheny Eye Institute, UCLA’s Schools of Medicine and Public Health, and the Institute for Medical Leadership.

Daniel attended UCLA and graduated with a BS in Biology, a MPh or Executive Masters in Public Health and MD from the School of Medicine. He also completed his study of human terartogens at Harvard Medical School.
A New Global Economy – A New Global Strategy

A new economic reality is re-shaping the way large business will be done in the future. Gone are the days of large scale consolidation that do not contribute to the core competency of the parent entity. Gone are the days when U.S. based businesses could feel safe and superior in their position as a global power to dominate foundational and emerging technologies. Also gone is the ability to ignore the rest of the world as potential competitors. Today even third-world nations have substantively growing trade economies because they are willing to be price-competitive, practice-competitive and to run their business as tight and as lean as they need to in order to keep competitive while still maintaining quality. To succeed, business must be played on a global scale and those businesses that will succeed are those that are willing to invest heavily in identifying their key market differentiators and to create strategic business plans with affinity partners where both companies can benefit by staying focused on what they do best and then working to be a competitive leader in that sector of the marketplace.

Over the past two years, Magnetecs has been working to prepare itself for the new reality and opportunities the global marketplace offers. The diagram below illustrates Magnetecs’ strategy for capturing the market in the advanced medical device arenas it chooses to compete in.
“The future of minimally-invasive medicine is Robotics. Magnetecs’ CGCI is at the cutting edge of remote magnetic navigation. It is my vision to make sure Magnetecs becomes the “standard of care” when the history of advanced medical technology innovation is written.”

– Josh Shachar