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Enquiry No. 1
Dear Doctor,

With the dust somewhat settling on the new U.S. administration, we are perhaps at least getting a glimpse of what the future might be like. It is time for all of us to once again resume the process of planning for our future success. This issue is dedicated to that theme. We all need to gather the best information we have and forge ahead.

Do we know what the future holds for Orthopaedics? No, but it is a fact that the future demand for orthopaedic intervention is staggering if you examine the demographic data. Shirley Engelhardt herein gives a picture of just one segment of it.

A few things I think we can all predict for the rest of the year.

1. Continued sobering news of the global economy.
2. Increased pressure on you to do more for less.
3. Additional scrutiny of companies, surgeons and sales reps by the Federal authorities.
4. Evolution of orthopaedic practice business models to create increased efficiencies that you will require to thrive.

Teresa Ford’s article does an excellent job of reminding us that the playing field has permanently changed regarding the relationships between surgeons and industry. If we all accept this, we can better plan for a future with new rules.

That said, we continue our series on building a better practice through opportunities in ancillary services, obtaining financing for growth and intellectual property development, and provide valuable guidance to help you on your way to leveraging your ideas, as well as avoiding the legal pitfalls of alternative business models.

In future issues of this publication, we’ll focus on these changes and provide you the business tools you’ll need in response to them. If there are specific issues or challenges you wish us to address, let us know. We’ll put you in contact with the experts.

As we do each issue, we renew our oath to provide the tools you need to succeed in the future. We welcome your input.

John A. Engelhardt
Editor in Chief
The New

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Enquiry No 3
Earlier submitted articles, such as the initial series of the “Golden Rules” of patent law, were intended to acquaint the reader with guidelines, cautions and helpful suggestions that, if followed, could facilitate an inventor’s success in obtaining patent protection for his new and useful discovery. Later articles provided information and guidance regarding foreign application filing, licensing strategies and protecting the inventor’s intellectual property from would-be infringers. My most recent articles have focused on the realities of obtaining patent protection for his invention, only to find that the applicant who reached the end of his journey along the pathway to receiving a U.S. Patent is not really the end of the line, but only “build a better mouse trap and the world will beat a path to your door.” Let us first consider the preferred scenario—that the inventor/entrepreneur is free to consider several possible paths which he can follow to have his invention put to the good and beneficial use originally intended.

The inventor/entrepreneur can take the bold step of seeking to obtain financing and endeavor to develop his own manufacturing and distribution company to bring his invention to the market, he can choose to partner with another party having deeper pockets to accomplish the same end but with a shared risk, he can choose to assign the rights to his invention to another who hopefully will develop it to its best potential while the inventor is free to walk away with his reward, or he may choose to license, exclusively or non-exclusively, the right to practice his invention to others while he will hopefully enjoy a stream of royalty income for years to come. In the real world, not all of these possibilities will present themselves to the new patent holder and, if none of these pathways open to the inventor, the result can be post-patent depression. Let us now consider each of the possible paths on the second leg of the journey to developing and benefiting from a newly issued patent.

To obtain financing and follow the inventor/entrepreneur’s dream of building a company to develop and market the invention can be a daunting task, unquestionably filled with risk, but overflowing with possibilities. For the risk-adverse reader it will seem strange to hear that there are still today inventor/entrepreneurs such as this working to turn inventions into new start-up businesses that, with good fortune, will be big businesses someday. I have had the pleasure of working with a few inventors over the years who have also been extraordinarily successful entrepreneurs; but, such risk-takers are not among the majority of inventors receiving patents today. Their success is the result of a combined bounty of genius in discovering their invention and an equal portion of business acumen in traversing the potentially treacherous path of building a small business into a mid-sized or big business. It is definitely the road less traveled.

Partnering between the inventor and an established company that has the resources to develop the invention is another pathway that can be followed by the inventor as a way to bring the invention to market while sharing the risk with another party having already cleared the many hurdles to starting a successful business. Typically,
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this partnership relationship is accompanied by an assignment of the rights to the intellectual property with the inclusion of the inventor as an integral part of the company’s product development effort. Unlike a clear and complete assignment of the invention to another company, wherein the inventor can simply walk away with his financial reward, this partnership inextricably ties the inventor to the success or failure of the company such that the potential for reward is greater but the risk for loss is shared in the partnership. A primary concern for the inventor considering this route is to do due diligence in his decision to entrust the invention to a potential partner/company. A thorough study of the potential partner’s history of success or failure, other partners or lien-holders, financial strength of the company, marketing capacity and reputation in the relevant market among other aspects must all be carefully and independently investigated before shaking hands and placing the hard earned Letters Patent into the hands of a partner.

Outright assignment of the invention is many times a preferred path for the inventor who wants his invention to be developed to its fullest potential as early as possible and doesn’t want to assume any risk in the success or failure of the acquiring company. Another familiar adage, which has in the recent stock market activity lost much of its meaning, is “high risk – high gain; low risk – low gain.” A full assignment of the exclusive rights to the patented invention allows the inventor, patent assignor, to simply walk away with his financial reward and assume no risk. In contrast, an assignment of the invention that turns over the ownership of the patent to the assignee but does so with a pay-out of the price of the assignment over a period of time generally will provide a lesser financial reward initially, because the inventor is assuming some risk that the assignee company might fail and in that failure stop any down-the-line payout or buyout of the price of the assignment. In negotiating such a timed buyout, the inventor can, since he is assuming some risk, require a larger total price for the assignment than if the inventor were to accept no risk and take a lump sum payment and simply walk away with his reward. In cases where the inventor/patent assignor accepts terms for a buyout over a period of time, it is, as with the partnership pathway, critical that due diligence in the study of the company/assignee be done.

The more common pathway to developing and marketing the new invention that is chosen by inventors is to license the patent rights to an established company. Negotiating and drafting a mutually beneficial licensing agreement is a task far more difficult than could possibly be described in the whole of this article. Another adage well-known in the field of intellectual property is, “licenses are the stuff from which litigations are made.” Legal disagreements resulting in high dollar litigations very often come from license agreements in which one party has over-reached and presumed to practice claims in the patent for which a license was not granted. Other contests often arise from license agreements.
wherein one party disputes the royalties that are due and payable. Virtually every aspect of a license agreement has the potential to create a disagreement of interpretation, if not outright breach of contract, and thus licenses create an environment of risk for the patent owner/licensor, who by the licensing of his patent rights must necessarily place some degree of trust in the licensee for compliance with the very carefully negotiated agreement. Such issues also frequently arise in cases where two or more companies, each having their own valuable intellectual property, have cross-licensed some of that intellectual property one to the other. With the higher level of risk, the potential for a higher financial return to the inventor/assignee can be expected. Given the potential for conflicts in license agreements, this expectation of higher earnings can only be realized if the inventor or patent holder/licensor exercises due care in negotiating the terms of the license.

Having briefly discussed the pathways for developing the patented invention that are open to the inventor/new patent holder, it is time to consider the downside, the post-patent depression that may descend on the inventor when none of those invention development and marketing pathways readily present themselves on the day the new patent issues.

Unfortunately, the possibility is sometimes a reality that the inventor will be eagerly standing at his front door holding a newly issued patent for the “better mousetrap” only to hear the deafening silence of no one knocking. Further, rather than adhering to the naïve belief that the world will “beat a path to your door,” it is more prudent to consider the likelihood that, if the invention is truly something of great value, the door through which the world may come to obtain the invention will be the back door, not the front. Like a thief in the night, an infringer may simply step through the back door, copy the invention for his own use and walk away with the rewards for which the inventor has patiently labored. The possibility of these circumstances arising can be depressing at a time when the holder of a new patent should be rejoicing. Not wanting to dwell on the negative, the remainder of this article will discuss a few basic measures that an inventor can take into consideration that may help prevent the possibility of post-patent depression.

Of primary importance, the inventor should be proactive in preparation to follow one of the above described preferred pathways to developing and marketing his invention. The inventor should begin this preparation for the next leg (post patent issue) of his journey as soon as possible after the patent is filed. In fact, using the protection afforded by the use of confidentiality agreements, early liaisons with potential lenders, partners, assignees or licensees can begin prior to filing the patent application. Importantly, the inventor should not be so naïve as to believe that he can coast through the patent prosecution period and expect that when his patent issues, the world really will “beat a path to his door.”
case, the inventor must recognize that marketing his invention to potential development and manufacturing partners, investment partners, assignees or licensees is his responsibility, and the effort will require imagination, initiative and marketing skills.

For the inventor who tells himself that he has done all that he could to set his invention on the right pathway to development and marketing but still finds himself holding a U.S. Letters Patent that seemingly is suitable only for framing, the post-patent depression can be much more than disappointing. While disappointed, the frustrated inventor still believes in the value of his invention. He still wants to see it fully developed and marketed for the benefit of the public, and he undoubtedly would still like to realize some financial reward for his ingenuity, tenacity and expense in bringing the invention to the marketplace. The fact that the inventor still firmly believes in his invention, it is imperative that he use all means at his disposal to overcome his disappointment and grasp victory from the jaws of defeat.

As a former Marine aviator, I still recall the pleasure I had years ago of engaging in a friendly conversation with a Marine General officer of considerable reputation for his combat experiences while serving as a young company commander early in his career. In that conversation, I asked the General about a particular battle of which I had read where he distinguished himself by leading his company of Marines to turn a precipitous defeat into a legendary victory over a much larger force. He very briefly described that he had simply responded to the situation in the only way he could if he was to win the day. He then added that “Audacity and tenacity are the keys to success.”

I recite the General’s statement to me, not only because it brings back fond memories of a great leader I was honored to work with but because he had evolved the skills of the true success is to audaciously bring the invention to the marketplace. The initiation of startup companies, creation of development partnerships, assignments and licensing are among the pathways through which the inventor can achieve the successful development of his patented invention. Failure to consider every possible pathway to achieve a complete development and marketing effort could result in the ultimate failure of the invention.

This article is not intended as legal advice but is provided only to make the inventor/entrepreneur aware that successfully obtaining a U.S. Patent for his invention is not an end in itself but is only a milestone in the demanding journey to fully develop his invention. The jubilation of success or the depression of disappointing results are alternative outcomes that lie primarily in the hands of the inventor.
Progress Update: A New Technology Platform for Arthroscopy

In the July/August 2007 issue of ORTHOPAEDIC PRODUCT NEWS, Dr. Marc Philippon introduced the industry to Micro-Imaging Solutions, LLC's (MIS) extremely small and high resolution CMOS (Complimentary Metal Oxide Semiconductor) sensors. (See Exhibit 1.) The technologically-advanced nano-sensors are targeted to benefit a number of surgical applications, including arthroscopic visualization. In July, the company had completed the design and just received the first generation of its broadly-patented sensors. This milestone confirmed their ability to produce its custom sensors inexpensively while maintaining the high visual quality demanded by surgeons.

Exhibit 1: Sensor assemblies designed initially for arthroscopic and laparoscopic applications. Sensors are very applicable for flexible or "steerable" scopes, as well.

Since Dr. Philippon’s introduction, the company has achieved several additional and significant milestones toward bringing this exciting technology to the market. First, MIS has demonstrated a high quality image from all three of its initial custom CMOS sensors and received the first commercial order for its CMOS sensors from one of the company’s existing licensees. Second, feasibility studies have shown that MIS will significantly improve its image in the very near future with advancements in pixel technology. This improvement will allow an enhanced image as well as a decreased physical profile of its designs to accommodate smaller diameter endoscopes. Finally, and in keeping with its focus on intellectual property protection, MIS received issuance of its 18th patent in late 2008, which covers the European Union.

Micro-Imaging Solutions has taken delivery of its second generation of CMOS sensors, with the smallest being 1.8 mm to fit in the distal tip of a standard 4 mm diameter arthroscope. (See Exhibit 2.) MIS’ existing and future licensees will target this technology in a variety of scope formats and sizes. MIS’ technology will provide for a disposable and comprehensive scope system from the tip of the scope through and including the cable that plugs into the control box situated on the existing video tower. The MIS system can be fully compatible with all existing tower systems. Currently, the image must pass through the entire optical path of the scope, eyepiece and coupler before it is collected by the CCD sensor mounted within the camera head. Intuitively and by design, the MIS image is much improved since the image is captured at the distal tip. Dr. Philippon accurately indicated that the image is the most important element required to perform the arthroscopic or endoscopic procedures when he stated, “If you can’t see, you can’t perform the procedure.”

Exhibit 2: 4mm arthroscope optics and sensor illustration.

continued on page 13
Rigid endoscopes have seen little change in the past 50 years, yet they remain the standard for visualizing joints and other cavities. Unfortunately and as we have all experienced, image quality (including light transmission) degrades over time due to the rigors of surgical use, cleaning, care, sterilization and storage of these delicate and costly devices. Additionally, the high cost of the scopes often limits inventory availability, resulting in surgical delays while consistently over-extending the normal life expectancy of compromised scopes. The arthroscopic operating room environment is full of special challenges that negatively affect the life expectancy of arthroscopes when used in conjunction with shavers, burrs and radio frequency (RF) wands.

Excessive “fogging” is another common problem associated with the environment in which the scopes are used or as the trend toward “autoclaving” scopes and camera heads increases. Distension media can invade the inner workings of the optical path and form condensate on the optics as the system heats up with the electronics, fiber optic light and the body temperature of the patient, as well as the surgeon’s hands. Sterilization by steam autoclave sounds good in theory, but has not seen acceptance due to its limitations including time delays as the system cools, fogging from the extreme variance in room temperature fluids to devices that were just exposed to > 280°F, and the reduction in useful life to the equipment from exposure to an incredibly harsh process.

Without exception, each endoscopic company offers a program to repair or refurbish scopes and camera heads. This again sounds good in theory, but several undesirable issues associated with these “solutions” arise. First, there is a significant ongoing expense to participate in these programs. Second, it remains an unknown whether the refurbished scope is much better than the one that went out. The optics may be perfect, but the fiber optics degrade over time and are not necessarily acceptable as the fibers are extremely difficult or impossible to replace. A quality and usable image is extremely dependant upon appropriate light transmission. Lastly, and of great importance to me, is the timing of the failure to provide a quality image, as it generally results in delays as we start our procedures. The scope or camera head is generally identified as a problem at the most inconvenient and costly time: when a patient is under anesthesia. Delays in the procedure and the “snowball” effect experienced throughout the day’s surgical schedule are real. Many scope-related problems are ongoing ones associated with the existing

continued on page 14
technology, A typical situation appears in Exhibit 3. Even reusable videoscopes cannot be assessed for condition unless connected intraoperatively. Delays attributed to faulty endoscopes, sterilizer issues, leaky couplers, inefficient fiber optic cables, non-working umbilical cables and introducer systems are eliminated with the MIS disposable technology.

Exhibit 3: Image generated from a direct couple video scope attached to an HD camera. The focus ring was “frozen” and there was a defect in the center of the image. This was swapped out intra-operatively, but took several minutes and resulted in significant repair costs to the facility. This is eliminated with MIS disposable technology.

The high costs associated with scope repairs have created the market for “third party” repair companies. These companies offer “savings” to facilities, but do not receive access to original parts or even the original manufacturers’ design specs, so the “repair” results are generally inconsistent and occasionally, clinically unacceptable. Repairs and the downtime and effort associated with damaged scopes represent important issues and expenses that occur in every facility that performs endoscopic procedures.

The MIS imaging products address existing problems while providing excellent image quality, pre-sterilized, “off the shelf” with economically significant efficiencies. As an owner of a surgery center, I am very aware of the current costs and limitations of the existing technology, and am excited by the solutions offered by MIS’ technology.

Historically, the endoscope market has experienced unsuccessful attempts to introduce “disposable” scopes, starting in the early 1990s. These early attempts failed for two reasons. Either the image was substandard compared to the existing, albeit inconsistent “reusable” image quality, or the product offering was only one piece of the multi-component video image chain. No benefit in economy or time savings was available to the user if the balance of the products required cleaning and re-sterilization prior to a subsequent procedure. Early disposable scopes were made from a “coherent” fiber optic bundle or inexpensive optics that did not meet adequate image quality standards to be accepted. In its current prototype design, the MIS arthroscope offers ten to fifteen times more resolution than those early attempts at disposable scopes. MIS’ approach (See Exhibit 4.) will mark the first time that those previous issues have been collectively resolved. Importantly, MIS’ product will not represent material incremental cost to the facility compared with the existing expense and ongoing inconvenience of the current endoscope systems.

Exhibit 4: MIS family of disposable endoscopes

There has been a significant marketing emphasis toward a high definition (HD) image as a clinical necessity in the OR, but arthroscopists have been able to see well enough to get the job done going back to the days of the tube cameras. I do not really believe that HD has as much clinical significance as is emphasized in the marketing brochures. I prefer a quality and consistent image after stepping away from the scrub sink, as I generally don’t find a resolution chart in a joint. Specifications obtained under ideal conditions are meaningless when challenged with the rigors of clinical utilization. The only thing more frustrating than an image from a defective scope is an HD image from that bad scope.

High Definition does not eliminate any of the issues mentioned earlier and, in fact, may increase costs for the facility. Initial acquisition costs should be higher and the HD camera will display defects more acutely in the optics, thus increasing the repair or refurbishment costs. Even the CCD-based HD systems are perceived to be “commodities” in today’s market, since every major market leader offers it and the starting point for the purchase includes a huge discount. There is no real differentiation between the companies’ product offerings, and price erosion has already commenced.

The MIS technology represents significant benefits that will provide market differentiation within the video endoscopic marketplace. It would be difficult to justify purchasing existing and historically problematic scope and camera technology once the CMOS benefits are introduced to the market through
MIS-licensed partners. MIS-licensed partners will offer solutions to substantial shortcomings associated with technology that hasn’t improved for decades. Upon examination, the cost of adopting this improvement is not materially-incremental relative to the ongoing built-in expenses currently encountered with existing products.

Administrators should recognize that there is a positive financial impact from the MIS technology, complementing the numerous clinical and technology benefits enabled by the MIS technology. They should examine the entire landscape or true cost of ownership involving the acquisition, maintenance and efficiency when comparing existing CCD-based technology with the future technology as represented by CMOS. The current or aspiring endoscopy companies that supply the technology should recognize the potential differentiation available for its sales efforts while providing long overdue and welcome solutions to widespread expensive and inconvenient problems.

The transition to CMOS-based scopes will be “seamless,” since the physical design will mirror designs used today and the only change will be the exchange of the CCU on our existing towers. The arthroscopist and Operating Room staff will welcome this new technology. Future options available to enhance MIS’ technology are just as exciting and desirable as the initial introduction of the CMOS technology. MIS is poised to support interchangeable angles of scopes and even eliminate several of the “tethers” we’ve worked with for years, including the fiber optic cable and the cable that connects to the control unit on the tower. Also, flexible tip scopes may be offered that will improve anatomical access while providing a high quality CMOS-based image, since the CMOS sensor is mounted at the distal tip of the scope.

Leslie S. Matthews, M.D., is Chief of Orthopedics at Union Memorial Hospital in Baltimore, Maryland where he also serves as Orthopedic Residency Program Director. He is an owner of the Greater Chesapeake Surgery Center. He can be reached at eric@micro-imaging.us.

Dr. Matthews received his B.A. degree from Johns Hopkins University and his M.D. degree from Baylor College of Medicine. He completed Orthopedic Residency at Johns Hopkins Hospital and fellowship training at Massachusetts General Hospital. He earned his MBA from the Sellinger School of Business at Loyola College in Baltimore.

He is a Past President of the Arthroscopy Association of North America and currently serves as Chair of the Board of the Journal of Arthroscopic Surgery. He is Arthroscopic Section Editor for Orthopedics Today, has held numerous editorial positions, and is team physician for the Baltimore Ravens.

Enquiry No 24

PRODUCT FEATURES

UPPER EXTREMITY

A.M. Surgical CPX

The A.M. Surgical CPX is a non-bridging, external fixation device designed for minimally invasive treatment of displaced and non-displaced distal radius fractures. Through its cross-pin configuration, the device provides rigid fixation of the fracture while maintaining reduction in all radiological parameters. Of note is the ability to angulate each K-wire ten degrees from the center of the wire’s respective guide, facilitating fragment capture. The fracture alignment can be radiologically evaluated with no obstruction in the AP plain and with minimal obstruction in the lateral plain. The device is relatively unobtrusive and allows for mobilization of the wrist for early rehabilitation.

The CPX uses 0.062 K-wires and has three K-wire guides, both distal and proximal, with the addition of two subchondral, transverse K-wire guides (6 options for K-wire placement).

The CPX is a non-bridging alternative for avoiding the drawbacks of spanning fixators and ORIF.

A.M. Surgical, Inc.
Tel: 800-437-9653
www.amsurgical.co
Enquiry No 25

AOS Humeral Nail System

The AOS Humeral Nail System consists of both Short and Long Intramedullary Nails. The system includes a 15cm Proximal Nail which offers advanced fixation for 2-, 3- and some 4-part fractures of the proximal humerus. With a proximal bend of 6 degrees, the AOS short nail is best suited for simple 2-part fractures of the proximal humerus involving the surgical neck of the humerus and proximal third humeral fractures without comminution. In these scenarios, the bend facilitates an easier entry portal attainment and nail insertion with an incision just medial to rotator cuff insertion.

The Long Humeral Nail is primarily indicated for humeral shaft fractures which are inherently not prone to varus malposition. The lateral portal design allows insertion just medial to the rotator cuff and facilitates easier portal attainment and nail insertion. The Long Nails range from 20 to 30mm in length and 7 to 9mm in diameter.

As a design rationale, the AOS Humeral Nail System was formulated by closely examining past challenges presented in humeral nailing procedures. With these challenges in mind, AOS has included new and innovative features to the instruments and implants.

Advanced Orthopaedic Solutions
Tel: 866-229-7686
www.aosortho.com
Enquiry No 26
Tensioned Rotator Cuff Repair Without Suture Anchors

Author: Daniel G. Cerundolo

Arthroscopic Innovations, LLC, has developed two patent-pending products for arthroscopic rotator cuff (RC) repair. The Intersector® is an instrument that forms transosseous tunnels for use in either open or arthroscopic cases. It allows the surgeon to place both entry and exit tunnels at any location in bone. Biocleat® is a bioabsorbable implant which provides tensioned fixation on a cortical surface.

Utilization of these two developments now enables a surgeon to arthroscopically provide a tensioned RC repair without the use of suture anchors. The system may be used for primary RC repairs, or for arthroscopic RC revisions, even when bone integrity is compromised by existing anchors.

These developments provide a less invasive and significantly more cost effective technique for RC repair. Our first product introduction is due to be in clinical use during the first quarter of 2009. During 2009, surgical skills workshops will be conducted throughout the U.S. The schedule of these workshops will be posted at our website, www.arthroscopicinnovations.com.

The mission of Arthroscopic Innovations is twofold: to provide platform solutions to challenges of current arthroscopic techniques, and to introduce innovations that enable open orthopaedic cases to be done arthroscopically.

For more information, contact admin@arthroscopicinnovations.com.

Enquiry No 27
Control At Your Fingertips
KARL STORZ Powershaver SL – the highest speed and the most stable torque available today
Alternative Surface Technology for Knee Implants

In February 2009, Aesculap Implant Systems launched its Alternative Surface (AS) Technology, an advanced coating system for knee implants that offers a surface with advantages over Cobalt Chrome (CoCr). The coating, which reportedly produces less wear and releases significantly fewer metal ions than CoCr, will be applied to Aesculap’s Columbus knee.

The seven-layer coating is composed primarily of Zirconium Nitride, a durable ceramic material that creates a harder and more durable surface than traditional implant materials. In ISO wear testing, the surface has shown wear rates of just 3.5 mg/million cycles. ISO-certified laboratory testing also indicated that the release of Ni ions has been significantly reduced. Additionally, the design of the seven-layer coating aids in the prevention of mechanical ablation, a separation of the coating from the substrate, which may be a shortcoming of some mono-layer coatings.

The Columbus knee system features a full portfolio of AS-coated components, including Femur and Tibia components as well as Tibial Augments and Stems.

Aesculap Implant Systems, Inc.
Tel: 866-229-3002
www.aesculapimplantsystems.com
Enquiry No 28

LapWrap™ Positioning Pad

Innovative Medical Products introduced the LapWrap™ Positioning Pad, designed to secure patients’ arms during laparoscopic and head/neck orthopaedic procedures. The soft foam pad not only positions limbs during surgery, but also organizes IV tubes and leads for anesthesia.

The latex-free pad is manufactured for single use and is universally sized. LapWrap also protects the neurological structures of the elbow and acts as a warming blanket for the patient. LapWrap utilizes hook and loop fasteners that are easily configured for quick securing of a patients’ arms. The pad can be trimmed with scissors for better viewing of wire leads, tubing or connections.

Innovative Medical Products, Inc.
Tel: 800-467-4944
www.innovativemedical.com
Enquiry No 29

PATRIOT SIGNATURE™ for MILDERTM TLIF

Globus Medical introduced the PATRIOT SIGNATURE™ TLIF Spacer, designed for Transforaminal Lumbar Interbody Fusion. SIGNATURE is the latest addition to Globus Medical’s MILDERTM Spine Care portfolio (Minimally Invasive, Less Disruptive, Earlier Recovery).

The SIGNATURE TLIF Spacer system includes an articulating implant that enables surgeons to use a single instrument, from insertion through final placement, to deliver the spacer into the biomechanically ideal position through a portal or small incision. Ease of placement allows the surgeon to restore the natural lordotic alignment of the spine while employing an MIS approach. The system is designed to permit preservation of a significant portion of the musculature that lies between the skin and the surgical site on the spine while using a portal or mini-open technique.

The MILDERT portfolio encompasses a holistic approach to spine care that integrates minimally invasive surgical techniques with implants, instrumentation, and education designed to lessen the disruption to a patient’s anatomic structures and natural range of motion in order to facilitate an earlier, pain-free recovery.

Globus Medical, Inc.
Tel: 610-415-9000
www.globusmedical.com
Enquiry No 31

VascuTherm™ Iceless Cold Therapy, Compression and DVT Prophylaxis Therapy

The VascuTherm™ by ThermoTek delivers a unique and proprietary thermal compression therapy solution in one easily transportable device. Its solid-state technology eliminates the need for ice, offers precise temperature control for preventing thermal tissue damage and delivers exceptional reliability. VascuTherm™ offers DVT prophylaxis through its programmable multiple treatment modalities, combining heating/cooling temperature management with vascular compression.

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Legal Issues Concerning the Structure of Ancillary Services Arrangements

For many orthopaedic surgeons today, the development of ancillary sources of practice revenues is absolutely essential to financial health. As with all things medicolegal, however, this is not as easy as it might seem at first blush.

Various state and Federal laws regulate the extent to which physicians can legally refer patients to facilities or ancillary services in which the physician has ownership interest. This article focuses on Federal laws such as the Stark regulations and the Federal anti kick-back law. Keep in mind that each state also has its own laws which likely apply and which may impose additional obligations on physicians seeking ancillary sources of income.

The laws summarized below are complex and carry significant penalties for violations. This article is intended as an overview only, and is not to be construed as legal advice. Physicians considering creating or buying into one or more ancillary service modalities are urged to consult with an experienced health law attorney.

The Stark Facts
The Stark laws, named after their original sponsor, Representative Pete Stark, (D-CA), were enacted in 1989 and took effect in 1992 (Stark I). Stark I applies only to Clinical Laboratory Referrals.

Stark II, enacted in 1993 and became effective in 1995, applies to “Designated Health Services” (DHS). Designated Health Services include Clinical Lab Services, Physical Therapy, Radiological Services (such as CT or MRI) and Durable Medical Equipment, among others. We now have Stark III, published September 2007, which became effective in phases between January 2008 and January 2009.

In summary, Stark prohibits physicians from making referrals for DHS to an entity in which the physician or his or her immediate family has an ownership interest, unless an exception applies. The Stark regulations are “strict liability” laws, meaning that there is no intent needed to commit a violation. If a referral of a Medicare beneficiary for DHS is made to a physician-owned entity without an applicable exception applying, the law has been violated.

Prior to the enactment of Stark III, the primary exceptions were the “In Office Ancillary Exception” and the “Lease and Personal Services Exceptions.” In the face of Stark III, the In Office Ancillary Services Exception remains the dominant exception to Stark’s physician self referral prohibitions. As discussed further below, Stark III and related developments such as the Anti Mark Up Provisions (which have been enacted not via Stark, but rather, as part of the Medicare fee schedule) appear to spell the effective end of the Lease Exception.

The In Office Exception Explained
The In Office Ancillary Services Exception allows physicians to own DHS providing entities and self-refer their Medicare patients to such entities as long as the DHS is provided in the same building in which the physician regularly provides non-DHS services to patients. As an example, a physician or his group might own an MRI scanner located on the ground floor of the same building in which the physician has his regular office, or even on a different floor. As long as the physician regularly provides non-DHS (in this example, services other than MRI scans) to patients and there are specific tests as to what constitutes “regularly”, no violation of Stark has taken place.

One of the primary goals of the In Office Exception is to enable convenience for patients to receive ancillary services while at their physician’s office receiving regular care and treatment. This goal is illusory if the physician does not “regularly” provide a “full range” of other services to patients at the location in question.

The Centralized Facility Exception
The Centralized Facility Exception is very similar to the In Office Ancillary Services Exception, with one key distinction: as noted above, arrangements structured under the In Office Exception may involve ownership of the DHS by separate individuals or groups of physicians as long as they all practice “in the same building.” By contrast, under the Centralized Facility Exception, a solo physician or an integrated Group billing under only one tax ID number can own a DHS-providing entity and send Medicare patients to that entity, even if the DHS services are provided in a separate building—even one miles away from the regular office of the physician’s practice.

Thus, under the Centralized Facility Exception a Group of physicians, each of whom bill for all of the Group’s services under one tax ID number, can practice in location “A” and own an MRI facility (for example) located at location “B” three miles from the group’s office. As long as only the members of the Group own the MRI entity (i.e. with no outside owners), there is no Stark violation.

Author: Doug Free

continued on page 21
The ASC Safe Harbor

Many orthopaedic surgeons own or want to acquire interests in ASCs. This allows the physicians to retain not only the professional component of the fees for the surgeries they perform, but also a portion of the facility fee.

One of the main requirements of the ASC safe harbor is that physician owners of the ASC be able to certify every 12 months that at least one-third of their medical practice income comes from performance of ASC appropriate procedures, and that they will perform at least one-third of those procedures at the ASC in which they hold an interest.

Similar to the rationale which underlie the In Office Exception to Stark, the logic underlying the ASC Safe Harbor concerns the fact that ASCs have been found to be more convenient and more cost-effective than other surgery facilities in some cases. These benefits are only realized if owners of the ASC are actively doing cases there as opposed to serving as passive investors who simply wish to draw profit distributions without using the facility on a regular basis.

Division of Revenue

As a final point with respect to this overview, it is very important to note that both Stark and the Anti-Kickback laws closely regulate how income flowing from permissible arrangements is distributed. In general, it is absolutely imperative that DHS (Stark) or non-DHS (such as ASCs, as one example) arrangements be structured in a manner which does not tie compensation to patient referrals.

As an example, assume that a group of orthopaedic surgeons owns an MRI under the In Office Ancillary Exception. Income from the MRI must not be distributed based on usage of or referrals to the MRI facility. Instead, a permissible method of dividing up MRI revenues would be to divide based on pro rata ownership percentages in the Medical Group, or based on overall productivity within the Medical Group, not counting revenues attributable to the MRI.

Similarly, owners in ASCs must receive profit distributions commensurate with their ownership percentage in the facility, NOT based on how many cases they do at the ASC. To deviate from these rules can lead to the imposition of severe fines and penalties including imprisonment.

Conclusion

In light of the economic challenges faced by the medical profession today, it seems almost a given that orthopaedic surgeons need to seek out means of developing ancillary sources of practice revenues. However, as the old adage goes, if you are going to do it, be sure you do it right.

Doug Free is a partner in the San Francisco law firm Kessenick, Phillips & Gamma, LLP, which focuses on assisting physicians, medical groups and medical specialty societies with health law and business issues. Mr. Free represents many individual physicians, medical groups and surgery centers throughout California and elsewhere, and he regularly advises physicians and groups in all areas of health and business law, including Stark, anti-kickback, antitrust, employment law and contracts, corporate matters, tax, insurance and regulatory matters, medical group formations, expansions and mergers. Mr. Free can be reached at 41-362-6414.

Enquiry No 32
No doubt, the current rollercoaster economic environment with all of the headline news, television and even Internet blogging focus has led many of us to assessments, opinions and assumptions. Unfortunately, many of these assumptions may unnecessarily impact your practice in a negative way.

One assumption is that it is impossible (or nearly so) to obtain financing, whether for a line of credit, equipment lease or receivable financing.

While it is true that the finance application process may require more information, and the due diligence process is now such that yesterday’s (pre-October 2008) “application only” product is largely a thing of the past, financial institutions and leasing companies are indeed lending. Not only is money available to doctors, but now more than ever is the time to strategize and prepare for your practice’s current financial health.

Let’s start with the basic question: What is your strategy? Do you have one? More importantly, do you have a financial plan which can secure lines of credit to ensure your financial flexibility, and the equipment necessary to maintain the level of surgery, and facilities that your patients need and demand?

While many questions are yet to be answered in finding solutions to the problems facing the global economy, a few givens exist for your practice. For example, we know that CASH IS KING.

We also know that technology innovations will demand that you update your capital equipment (C-arms, computers, phone systems) and reinvest in your practice on a regular basis. Additionally, we can predict that your practice will have repair and maintenance requirements, as well as unforeseen incremental operating expenses. With all of the unknowns, continued capital expenditures and working capital to maintain and grow your practice are imperative. Another way to say this is, you need to prepare for what you don’t know.

All too often, the thought process is that the surgeon will immediately inject the practice with money out of his or her own personal bank account. This may not be the best short or long term solution. A more prudent alternative is developing a cohesive program using various financial components that will allow you to reinvest in technology and meet your working capital needs.

Let’s discuss issue #1: technology reinvestment. You know that to maintain and grow your practice, you want to have access to the latest equipment. This is especially true for radiographic technology.

Also consider this: even if you don’t have the latest technology, your competition more than likely will. On the one hand, you and your partners may question how you are going to pay for that $100,000 C-arm. But on the other hand, can you really afford to delay purchasing the laser in order to maintain and grow your practice?

We can start to address these concerns by analyzing the costs versus the benefits. How many scans can you perform with the C-arm on a monthly basis? How much revenue will those scans generate? How many more procedures will this equipment allow you to perform? How much time will you save by doing these procedures “in-house” with state-of-the-art equipment rather than the equipment you currently use or outsource?

Let’s make some financial assumptions. Suppose you take that $100,000 piece of equipment and lease it for 60 months at an interest rate of 11 percent. That would mean that your payment is going to be about $2,180 per month.

Let’s also tell the truth about the future. If we were to say that your business will at best stay flat or even decline 10 percent over the next year without the new technology, is the investment of $2,180 per month an investment worth making? We have not yet factored in the depreciation benefits on your tax return, which are substantial.

Using this brief example, if you consider that between the time saved in operating efficiencies and the new potential revenue streams that will undoubtedly be created, add to that the depreciation advantages on your tax return, and the investment of new equipment is definitely worthy of your consideration.

While equipment leasing is a great solution to gaining and keeping your competitive edge, we’ve got to address issue #2: You don’t know what you don’t know! Whatever business life cycle you find your practice in—early to medium or even mature—solid and consistent working capital is key to maintaining profitability and
generating positive cash flow. Financial flexibility goes beyond saving for a rainy day, though having a safety net is just smart business. Establishing a line of credit can be a critical tactic in executing your strategic plan for your practice.

Let’s address some basic day-to-day realities. Do you need to consider marketing your practice and the new procedures you offer now that you’ve got state of the art equipment? Does your website need a makeover? Do you have a website? Does your back-office staff have access to updated software, database tools for billing and other types of patient tracking and communications? Is it time for new computers? Is your IT network stable? Do your facilities need a makeover? Is it time to move due to planned or unforeseen circumstances? If and when you do move, do you need to build-out your new facility? Will you need to add staff to handle a growing practice? Do you need to buy out a partner? Do you need to bridge the gap between receivables and payables?

We don’t know when, but we do know that eventually these and other day-to-day realities will need to be addressed. Depending on the circumstances, a decision and the resulting expenditures may have to be made quickly. If you aren’t prepared, productivity can suffer and operating cash flow can dwindle. Therefore, access to a line of credit is essential.

What about the costs? In other words, can you afford a line of credit? A line of credit could cost only seven percent; assuming a prime rate of five percent plus an additional two percent. If you tapped an entire line of $100,000, that would be a monthly payment of roughly $600. But with disciplined execution of your strategic plan, and other financial tools such as equipment leasing, you may never need to tap that line. Of course, being prepared in advance is the ultimate safety net. Perhaps the answer to the earlier question is that you can’t afford to be without a line of credit in the practice!

The truth is, both in times of economic uncertainty as well as high growth and seemingly endless opportunity, having a solid business plan and financial strategy and utilizing all of the financial tools available to you will help you maintain and or grow your practice, allowing you to do what you do best: service your patients.

Ed Mann is a co-founder and Chief Operating Officer of Ortho Practice Solutions LLC. In addition, he is the President of RC Leasing & Consulting, a national medical equipment leasing company. He can be reached at info@orthopracticesolutions.com.
Emerging Orthopaedic Technologies & Treatments

Recent FDA Clearances
December 2008 and January 2009

- Caltrix Resorbable Bone Void Filler (AG Digital Technology)
- RimClose Bone Anchor (Anulex Technologies)
- Comet Anterior Cervical Plate (Apollo Spine)
- Silicone PIP (Ascension Orthopedics)
- Suture Anchor (Extremity Medical)
- Revolve Stabilization System (Globus Medical)
- Hav-Lok Bunion Correction System (Instratek)
- Single-use PERPOS PLS System (Interventional Spine)
- EOS Spinal System (Korea Bone Bank)
- Novel Spinal System (Medyssey)
- Bone Plates and Screws (Microware Precision)
- MaxTorque Mini Cannulated Screw (OrthoHelix)
- Pediloc Locking Plate (OrthoPediatrics)
- Collagen Scaffold (ReGen Biologics)
- Newport Spinal System (Seaspine)
- Phenix Cervical Interbody Device (Spinal Devices)
- Ellipse Lumbar Posterior Osteosynthesis System (Spinearti)
- Proximal Humerus Scaffold Fixation System (TOBY Orthopaedics)
- General Spinal System/GSS, Intramedullary Nail (Trauson Medical)
- Phantom Plus Cage (US Spine)
- Xycor Spinal Implant (Vertebration)
- FDA 510(k) Releasable Database, 12/08 and 1/09

Studies suggest that proactive measures such as increased use of bone density testing, education and home health programs may reduce hip fracture rates by an average of 37.2% and by up to 50% among those at risk. (Kaiser Permanente Southern California, 11/3/08)

In a review of the 1st 537 U.S. Birmingham Hip Resurfacing procedures, serious complications were observed in 32 cases, including 10 in which the femoral neck fracture post-op. Nine of the 10 femoral fractures occurred in either female patients or those over the age of 55. Eight fractures occurred in cases where surgeons had performed 10 or fewer hip resurfacing surgeries. (HealthDay News, 11/14/08)

Engineers have created a synthetic version of a natural “superglue” created by sandcastle worms that live in the sea, and are investigating application for the substance in the repair of small bone fractures. In lab tests, a 1st-generation prototype performed 37% as well as commercial superglue. The product could enter animal testing within two years. (University of Utah, 11/25/08)

Studies of 51,000 hip revisions performed in the U.S. between 10/05 and 12/06 revealed the most common cause of implant failure to be dislocation of the implant (~23% of cases), followed by mechanical loosening (~20%) and infection (15%). (HealthDay News, 1/2/09)

Studies suggest that 3T (Tesla) magnetic resonance imaging (MRI) is able to detect bone bruises, cysts and ligament tears in the wrist, and may eliminate the need for an invasive arthroscopic procedure. (ScienceDaily, 1/6/09)

Researchers are developing a method of producing synthetic bone using techniques normally used to make catalytic converters for cars. The technique involves extrusion of the implant material through a mold to produce a 3-dimensional honeycomb texture with uniform pores throughout. The material can then be sculpted by the surgeon to precisely match the defect. After implantation, bone cells will be transported into the implant and begin to form new bone. (University of Warwick, 12/2008)

Researchers reported a 95% success rate in the treatment of plantar fasciitis by using a combination of “dry-needling” and steroid injections guided by ultrasound. (Radiological Society of North America, 12/2/08)

Studies of the Harris-Galante-1 acetabular metal cup, one of the 1st cementless designs, revealed that the device remained fixed in place in 95% of hip revisions at 20-year follow-up. (Rush University Medical Center, 2/2/09)

Studies suggest that performing arthroscopic repair of the labrum following shoulder dislocation in young patients may result in better patient-reported outcomes and reduce likelihood of a 2nd dislocation from >80% to <10%. (HealthDay News, 2/2/09)

Study results indicate that MR arthrography was more accurate than conventional MRI in the diagnosis of tears in shoulder tissue. (News-Medical.net, 2/7/09)

Researchers are studying the immune system of llamas to develop potential treatments for rheumatoid arthritis and other diseases. Tiny antibodies found in llamas and camels (~1/10 the size of human antibodies) may be able to settle into the crevices of joints to prevent arthritis. (WSJ.com, 2/17/09)
### Ticker Track (Based on close of business, 1/31/09)

<table>
<thead>
<tr>
<th>Company</th>
<th>Ticker Symbol</th>
<th>52-Wk High</th>
<th>52-Wk Low</th>
<th>Close</th>
<th>Chg vs. Prior Mo.</th>
<th>Chg vs. Prior Yr.</th>
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<tr>
<td>aap †</td>
<td>AAQ</td>
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<td>1.28</td>
<td>1.36</td>
<td>-30.3%</td>
<td>-55.4%</td>
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<td>Alphatec Holdings</td>
<td>ATEC</td>
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<td>1.51</td>
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<td>ArthroCare</td>
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<td>BioMimetic Therapeutics</td>
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<td>8.07</td>
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<td>-45.79</td>
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<td>co.don AG †</td>
<td>CNW</td>
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<td>0.62</td>
<td>0.93</td>
<td>1.1%</td>
<td>-46.6%</td>
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<td>Corin Group ††</td>
<td>CRGL</td>
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<td>0.78</td>
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<td>curasan †</td>
<td>CUR</td>
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<td>3.01</td>
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<td>Exactech</td>
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<td>Inion ††</td>
<td>IIN</td>
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<td>0.01</td>
<td>0.02</td>
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<td>-94.6%</td>
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<tr>
<td>Japan MDM§</td>
<td>7600</td>
<td>4.48</td>
<td>1.61</td>
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<td>-19.2%</td>
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<td>MAKO Surgical</td>
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<td>6.98</td>
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<td>NuVasive</td>
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<td>37.34</td>
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<tr>
<td>Orthofix</td>
<td>OFIX</td>
<td>55.28</td>
<td>8.65</td>
<td>15.96</td>
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<td>Orthovita</td>
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<td>Osteotech</td>
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<td>1.60</td>
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<td>134.4%</td>
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<td>RTI Biologics</td>
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<td>-69.4%</td>
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<td>Smith &amp; Nephew</td>
<td>SNN</td>
<td>69.20</td>
<td>30.27</td>
<td>36.36</td>
<td>12.6%</td>
<td>-46.0%</td>
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<tr>
<td>Stryker</td>
<td>SYK</td>
<td>70.56</td>
<td>35.38</td>
<td>42.24</td>
<td>5.7%</td>
<td>-36.9%</td>
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<tr>
<td>Symmetry Medical</td>
<td>SMA</td>
<td>21.99</td>
<td>5.91</td>
<td>6.85</td>
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<td>-62.4%</td>
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<tr>
<td>Synthes †</td>
<td>SYST</td>
<td>136.16</td>
<td>108.31</td>
<td>121.50</td>
<td>-2.3%</td>
<td>-2.5%</td>
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<tr>
<td>TiGenix †</td>
<td>TIG</td>
<td>3.43</td>
<td>2.95</td>
<td>3.43</td>
<td>3.9%</td>
<td>-20.8%</td>
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<tr>
<td>TranS1</td>
<td>TSON</td>
<td>16.50</td>
<td>4.55</td>
<td>6.25</td>
<td>-13.3%</td>
<td>-57.2</td>
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<td>Wright Medical Group</td>
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<td>1.5%</td>
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<td>Zimmer Holdings</td>
<td>ZMH</td>
<td>80.92</td>
<td>34.10</td>
<td>36.40</td>
<td>-9.9%</td>
<td>-53.4%</td>
</tr>
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</table>

† Converted from Euro to USD; 1€ = 1.285 USD.
†† Converted from British Pound to USD; 1£ = 1.4512 USD.
‡ Converted from Swiss Franc to USD, 1CHF = 0.9327 USD.
§ Converted from Yen to USD, 1¥ = 0.0112 USD.

### Company Financials’ 2008 vs. 2007

<table>
<thead>
<tr>
<th>Company/Ticker Symbol</th>
<th>Sales (SMM) vs. Prior</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy</td>
<td>$4,989.0 +8%</td>
</tr>
<tr>
<td>U.S.</td>
<td>$2,803.0 +6%</td>
</tr>
<tr>
<td>Ex-U.S.</td>
<td>$2,186.0 +8%</td>
</tr>
<tr>
<td>Hips</td>
<td>+11%</td>
</tr>
<tr>
<td>Knees</td>
<td>+6%</td>
</tr>
<tr>
<td>Spine</td>
<td>+8%</td>
</tr>
<tr>
<td>Sports Medicine</td>
<td>+12%</td>
</tr>
<tr>
<td>SYK</td>
<td>$6,177.3 +11%</td>
</tr>
<tr>
<td>Implants</td>
<td>$3,967.5 +11%</td>
</tr>
<tr>
<td>Instruments</td>
<td>$1,209.3 +15%</td>
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<tr>
<td>Endoscopy</td>
<td>$940.5 +8%</td>
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<tr>
<td>ZMH</td>
<td>$2,894.0 +3%</td>
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<tr>
<td>Hips</td>
<td>$1,280.0 +1%</td>
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<tr>
<td>Knees</td>
<td>$1,763.0 +6%</td>
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<tr>
<td>Extremities</td>
<td>$121.0 +15%</td>
</tr>
<tr>
<td>Trauma</td>
<td>$221.0 +5%</td>
</tr>
<tr>
<td>Spine</td>
<td>$231.0 +16%</td>
</tr>
<tr>
<td>Ortho Surgical</td>
<td>$278.0 -14%</td>
</tr>
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### FISCAL 2Q09 VS. 2Q08

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales (SMM) vs. Prior</th>
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</thead>
<tbody>
<tr>
<td>BME</td>
<td>$643 +9%</td>
</tr>
<tr>
<td>Reconstructive</td>
<td>$483.3 +10%</td>
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<tr>
<td>Fixation</td>
<td>$58.0 +4%</td>
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<tr>
<td>Spinal</td>
<td>$55.3 +9%</td>
</tr>
<tr>
<td>Other Products</td>
<td>$46.2 +6%</td>
</tr>
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</table>

Company news releases, 1/09

*Orthopaedic product sales only.

Constant currency.

In order for a company to qualify for inclusion in the Orthoinvestor Update, orthopaedics must represent at least 60% of its revenues.
Brad Bender, President and
Norman Eckley, Vice President
Sales & Marketing
Medartis, Inc.

Bradley Dean Bender was appointed President of Medartis, Inc. in 2008. Medartis, Inc. is owned by Medartis, AG, headquartered in Basel, Switzerland, with their domestic headquarters in Kennett Square, Pennsylvania. Mr. Bender has over 20 years experience in the area of trauma orthopaedics and has a background in medical start-up companies.

Mr. Bender oversees all U.S. operations of Medartis. In addition to overseeing daily operations, he is responsible for developing partnerships with surgeons and residency programs as well as other companies that complement the Medartis range of services and products. Medartis is a global manufacturer of orthopaedic implants for the facial skeleton, forearm and hand.

Norman Eckley, Vice President Sales & Marketing, began his orthopaedic career as a field sales representative for Howmedica in 1985. He achieved numerous individual sales accolades during his tenure with Howmedica and then Stryker Orthopaedics before moving into sales management in 2000. Mr. Eckley continued with a successful sales management career at Stryker Orthopaedics until his departure in June 2006 to join Medartis.

Mr. Eckley is responsible for managing the development of the sales team and sales training. Additionally, he directs the Medartis marketing efforts and educational endeavors.

ORTHOPAEDIC PRODUCT NEWS (OPN): Medartis has a unique philosophy and pedigreed history. Tell us about it.

Norman Eckley (NE): The Medartis philosophy has been shaped by the pioneering achievements of the Straumann Group in metallurgy, fracture fixation and implant design.

In 1954, Professor Reinhard Straumann founded the Institut Straumann AG in Waldenburg, Switzerland, which specialized in the fields of metallurgy and physics for the clock and watch making industry. Working closely with the AO (Association for the Study of Internal Fixation), his son, Dr. Fritz Straumann, merged the company’s expertise in metallurgy and physics with medicine to apply the specific metallurgical and physical findings to the development and production of metal implants for the surgical management of fractures. Members of our management team have been involved in designing and manufacturing trauma products for over 30 years.

OPN: When did Medartis enter the US market and how did this come about?

NE: At the end of 1989, the institute Straumann AG sold its Osteosynthesis division in the framework of a management buy-out. From 1990, Straumann Group, under the leadership of Dr. h.c. Thomas Straumann, concentrated exclusively on oral implantology.

In 1997, Dr. h.c. Thomas Straumann formed Medartis AG, thereby returning to the field of fracture fixation in craniomaxillo-facial surgery. Medartis continued the development in metallurgy. In 2002, the Medartis Group expanded its product portfolio, entering the orthopedic and hand surgery market in Europe. In 2005, the expansion of the new factory in Bretzwil (Switzerland) coincided with FDA clearance of the Aptus Hand and Aptus Radius Systems and entrance into the U.S. market.

In May 2009, Medartis will move into their new headquarters in Basel and continue the story of success.

OPN: The Distal Radius and Hand markets are extremely competitive. Where are you positioned?

Brad Bender (BB): At last count, there were 37 competitors in the U.S. Over the past three years we have gained the reputation for high quality implants and exceptional service, allowing Medartis to become one of the fastest growing orthopaedic companies in

continued on page 29
the U.S. With this continued growth, we expect to rank in the top five at the end of 2009.

**OPN:** Medartis seems to have a long history of success. How is the market in the U.S.?

**BB:** Following two years of triple-digit growth, we continue to grow at the same pace in 2009 by converting surgeons and institutions to Medartis weekly. We have continually expanded our sales team and marketing efforts and invested in education and training, while maintaining our focus on our long term vision. We are now approaching 5,000 distal radius cases in the U.S., so we now have significant clinical history from which to gain insight and tailor our efforts to the needs of the customer.

**OPN:** Who are your primary customers and what do they see in Medartis?

**BB:** Medartis has focused a great deal of time and energy on members of the various hand societies and resident education programs. Historically, this market segment has recognized and appreciated the unique features of our products. More recently, though, trauma and general orthopaedic surgeons are finding our products user-friendly. Medartis also recognizes the importance of education and encourages research, training and development. One example of this is through The International Bone Research Association (IBRA, www.ibra.ch), a financially independent, internationally oriented non-profit organization for specialized clinicians and research scientists. The third annual IBRA Scientific Seminar will take place in Basel, Switzerland in May. We are also excited to announce our first U.S. meeting which is being planned for November 20 - 21, in Miami, FL. Additionally, we continually support sawbones and cadaveric workshops throughout the year.

**OPN:** What is unique about the Medartis® TriLock® System?

**NE:** The TriLock® system is a multidirectional and angular stable technology that allows the screw to be angled ±15° and then locked into the plate. (See Exhibit 1.)

The locking mechanism can be described as a three-point friction-locked “cam” connection through radial bracing of the screw head in the plate. (See Exhibit 2.)

**Exhibit 2:** Details of TriLock locking mechanism

** Exhibit 1:** TriLok multidirectional locking screw

The stress is distributed over congruent surfaces of the screw head and inside the plate. Because there is no deformation of either the screw head or plate hole, the TriLock® screw can be re-locked in the same plate hole up to three times. This Polyaxial feature provides significant intra-operative flexibility by allowing the surgeon to position the plate where the anatomy dictates and angle each screw where the fracture dictates, leading to optimal fixation.

**OPN:** The locking technology sounds unique. Do all of the plates utilize it? What other features distinguish Medartis?

**NE:** The TriLock® technology is found in the Distal Radius System, as well as the locking plates of the Aptus Hand 2.0 system. This locking technology, coupled with a very strong Grade 4 titanium, allows Medartis to design both the distal radius (1.6mm thick) and hand plates (1.0mm thick) in a very low profile fashion. The advanced anodization process employed in our manufacturing results in an extremely smooth surface of the plates. Both of these features, along with many others, are focused on patient outcomes and minimally invasive surgical approaches.

The Aptus Distal Radius system includes plates for both volar and dorsal fixation, addressing fractures, as well as corrective osteotomies.

**continued on page 30**
OPN: How was the new Watershed Line Adaptive fixation plate received at the recent AAOS meeting in Las Vegas?

BB: We launched this newest distal radius design at that meeting and booth traffic was incredible! Interest from our surgeon customers suggest that we will need to manufacture around the clock to supply the leads and requests for sets. The move to our new manufacturing facility in May could not have come at a better time. (See Exhibit 3.)

Exhibit 3: New distal radius plate launched at 2009 AAOS meeting

OPN: Tell us about the Aptus® Hand set and how that fits in your portfolio.

NE: Our Hand System offers a variety of low profile straight, T, L and grid locking, non-locking and compression plates. The varieties of plates provide a wide range of capabilities to manage all fracture types with extreme versatility intra-operatively. (See Exhibit 4.)

Exhibit 4: Highlights of The Aptus hand system.

OPN: Are your instruments as unique as your implants?

BB: Yes, our instrumentation is finely crafted, lightweight and ergonomically friendly. The screwdriver utilizes a HexaDrive® tip to match the screws. The depth gauge is designed to be used “one-handed” and provides for precise measurement of the screw. The drill sleeve pin points angles for optimal fixation. The new Adaptive System combines these features for drilling, measuring and screw insertion through the attached drill guide block. Each device is best-in-class with the precision and quality being felt immediately.

OPN: What does the future hold for Medartis?

BB: We are a young company. We have aggressive goals and ambitions. Our product portfolio will continue to evolve as resources allow and we will constantly strive to maintain our technology advantage. We know there could be significant challenges ahead, especially given the global financial environment, but we will harden our resolve and commit our organization to delivering fracture products of the highest quality possible to our surgeon customers for the betterment of their patients.

Contact Medartis directly at info@medartis.com

Enquiry No 34

Grid locking plate to correct Metacarpal fracture  Mallet Fracture Plate

Much like the radius plates, all hand plates have rounded edges and polished surfaces for maximum soft-tissue protection. Additionally, Medartis® screws are self-tapping and feature an atraumatic, rounded tip which does not incorporate a “cutting flute” that could cause soft tissue damage on bi-cortical fixation.

The Aptus® Hand System has made a significant impact in our business. Until recently, it was the first and the only locking plate and screw system for treatment of metacarpal and phalanx fractures. It is quite unique and surgeons have found it to be a problem solver.

OPN: Your innovation extends even to your screw technology. Tell us more about the screws themselves.

NE: In addition to the atraumatic rounded tip, the screws offer a precisely cut thread profile for outstanding self tapping properties. The double threaded design of the locking screws aid with surgeon fatigue as the screw can be inserted with one half of the standard revolutions while offering increased screw anchorage. The tapered core diameter improves overall strength and stability. (See Exhibit 5.)

Exhibit 5: Screw technology detail
Multidirectional AND Angular stable

APTUS®
Hand and
Distal Radius System

New!
XL Plate
For the treatment of comminuted
distal radius fractures

System characteristics:
- TriLock® - locking technology
- Multidirectional AND angular stable
- Anatomical plate designs
- APTUS® - modular system components

TriLock®:
Locking Technology

locking Grid Plate

Locking Fracture Plate

Locking Frame Plate

Medartis Inc. * 127 W. Street Road * Suite 203 * Kennett Square * PA 19348 * USA
Phone 610 961 6101 * Toll free 877 406 BONE (2663) * Fax 610 961 6108
Enquiry No 12
For more information see www.medartis.com
SURGEON INTERVIEW

James Strickland, M.D.,
Andrew K. Palmer, M.D.,
Dale Dellacqua, M.D.
del palma Orthopedics, LLC

del palma Orthopedics, LLC (DPO) was recently founded by three orthopaedic surgeons and a small group of industry professionals. The initial focus is to bring rapid innovation to the extremity surgeon and patient.

In keeping with our series of interviews with surgeon entrepreneurs, we asked the founders about their experiences and motivations. We have left each of their responses intact, as it illustrates a fascinating breadth and strength of diverse perspectives, but at the same time, a common goal and vision.

James Strickland, M.D.
Dr. Strickland has had an outstanding career as a teacher, orthopaedic hand surgeon and leader. He is the senior member and founder of Reconstructive Hand Surgeons of Indiana and Clinical Professor of Orthopedics at the Indiana School of Medicine. During his career, he has published over 210 peer reviewed articles or book chapters and has given in excess of 800 lectures. He is the member of many hand societies about the world and has held leadership roles of: Founder and President of the Indiana Hand Center; the 44th President of the American Society for Surgery of the Hand and the 63rd President of the American Academy of Orthopedic Surgeons.

Dr. Strickland’s business interests in addition to being a founding member and board member of DPO include: Founder and Chairman of Dynomed, Medical Director and Board member of Chartlogic, CMO of Neumatrix, and, VP of Flagship Global Health. He has served as a consultant to and designing surgeon for Biomet, Inc.

Andrew K. Palmer, M.D.
Dr. Palmer has had an illustrious career as a teacher, orthopaedic hand surgeon and researcher. He recently retired from clinical practice but is still active in clinical research as Professor Emeritus at the Upstate Medical University in Syracuse, New York. He has 140+ peer-reviewed publications, has given numerous invited lectureships and is a member on many hand societies around the world. He has held the leadership roles of: acting chairman of the Department of Orthopaedic Surgery (twice) and director of the hand fellowship at the Upstate Medical University and was the 52nd President of the American Society for Surgery of the Hand.

Dr. Palmer’s business interests include being a founding member of del palma Orthopedics, LLC, Lotus Medical LLC and Ergo Designs Inc.; being a Director of DPO, BioMedical Enterprises, Inc. and being a designing surgeon for Biomet, DePuy and KMI as well as serving as a consultant to Small Bone Innovations.

Dale Dellacqua, M.D.
Dr. Dellacqua is a busy clinical upper extremity surgeon with practices at Reconstructive Hand Surgeons of Indiana and Bloomington Bone and Joint. He has written on rheumatoid arthritis and total wrist arthroplasty. He is frequently an invited lecturer or clinical instructor at courses dealing with conditions of the hand, wrist and elbow.

Dr. Dellacqua is the founding, designing surgeon of del palma Orthopedics and serves on the Board of DPO. He also serves as an expert consultant to Heron Capital of Indianapolis.

continued on page 33
How did you manage to make time to build your own enterprise?

James Strickland, M.D, (JS): The desire to make those inventions available to other surgeons and to realize a financial return on my innovations.

Andrew K. Palmer, M.D. (AKP): Experience in developing products with large orthopaedic companies led to a desire to develop methods to bring surgeon-generated concepts to market in an efficient and cost effective manner.

Dale Dellacqua, M.D. (DD): I have as strong belief that the surgeon who will use the product is the best driver for innovation. The surgeon has the unique ability to visualize the concept and see the result of an exceptional product with patient outcomes.

OPN: How were you able to finance your endeavors?

JS: I have personally financed most of the early development of devices that I conceived. Self financing beyond the very early development stages is too costly and, although I have patented several devices at an early stage, engineering, extensive CAD drawings, prototype development, revisions and clinical trials are far too expensive for most individual inventors to undertake. I have taken the initial drawings of most of my ideas to orthopaedic manufacturers and worked with their engineers to develop ideas into marketable products.

AKP: Inventors personally provided the finances to develop products early on. Additional funding was provided by personal contributions by the founders of DPO.

DD: Our company was primarily financed through close friends in the orthopaedic industry and its founders.

OPN: How did you manage to make time to build your own enterprise and maintain a busy practice?

JS: The conception of products to improve clinical practice and surgical methods is not difficult, but many ideas are lost because the motivation to create accurate drawings of new devices and surgical tools requires considerable time and effort, usually at the expense of practice or family time. Most of my early ideas resulted in rather crude Photoshop drawings that either died on the “drawing board” or led to self-financed prototype development. Most are taken to orthopaedic manufacturers who have the engineering expertise, the attorneys and the funds to complete the development process.

AKP: I had given up my clinical practice and was evaluating business opportunities when the concept for DPO’s initial product was presented to me by its inventor – Dr. Dale Dellacqua.

DD: The integration of product development and patient care has been one of the most enjoyable parts of starting this company. I have found that patients enjoy being part of advancements in technology. There is a sense of camaraderie that develops with patients. They seem to appreciate the effort to improve their outcomes and want to share in your success.

OPN: What was behind your decision to start your own orthopaedic company as opposed to selling or licensing your inventions to an existing company?

JS: Working with the large orthopaedic manufacturers is a very slow and difficult process that is often disappointing from a financial point of view. The manufacturers are often concerned with high end, high priced, large volume products such as hip and knee products and often are very slow to develop products that they perceive to be less profitable. In the end a small royalty is paid to the originator of an orthopaedic device and the entire effort may seem to be totally controlled by the manufacturer at the expense of the inventor.

Forming a small orthopaedic manufacturing company that could devote its efforts entirely to a specific niche such as upper extremity surgery seemed to make a lot of sense. The company could carefully select ideas from selected surgeons and bring engineering, manufacturing, legal and clinical expertise toward the rapid and high quality development of the product.

AKP: Although I have enjoyed an excellent working relationship with a number of existing orthopaedic companies, I sensed a need in the surgeon community for a small surgeon-driven company that could more quickly and effectively respond to their needs for innovative solutions to existing and emerging clinical conditions than could the existing orthopaedic community.

DD: I am interested in problem solving. In some instances, existing companies do not have the flexibility to rapidly modify design or production based on clinical situations. As an owner in the company, I can have a greater control over the quality of the finished product being the end user.

OPN: What was the biggest challenge you faced as a surgeon building an orthopaedic company?

JS: Selecting the right partners with the experience and expertise to set up the company properly and commit to the highest quality company and product development was an increasingly important factor from the outset. Gaining the initial start-up capital through investment by the founding partners was important, but the full scale implementation of product development requires substantial additional financing through a number of different sources including seed capital from family and friends, individual investors enamored by the company and its potential, or through private placement investments.

AKP: Our biggest and most exciting challenge has been assembling an outstanding and harmonious team of surgeons, engineers, managers and manufacturers to develop and support our products and the new ideas带来的 to us.

DD: The legal challenges are enormous and not my passion. I have spent a significant amount of time reading and attending conferences related to intellectual property.

continued on page 34
SURGEON INTERVIEW

continued from page 33

OPN: Were there times when you thought of giving up? What kept you going?

JS: I don’t think we ever considered giving up thanks to the dedication, commitment and enthusiasm of the founding partners.

AKP: Yes, there have been times when I as well as others on our team have thought of giving up, but we have always found a way around or through each obstacle that has arisen through the collective experience of members of the team. We have found that one of us had previously faced that same problem before and found a solution.

DD: I have never thought of giving up. I believe the intellectual property, products and potential benefits to patients are too great to ever quit.

OPN: If you could relive the experience what would you have done differently?

JS: So far, nothing.

AKP: Each time we conducted a lab to evaluate an early prototype product, I would have had assembled and made available for testing multiple variations of the prototype.

DD: I have been extremely happy with my current partners. I am fortunate to have met individuals as passionate about product design and patient satisfaction resulting from our products. I would not have done anything differently.

OPN: Do you think industry at large has responded properly to the needs of orthopaedic surgeons? What advice would you have for industry moving forward?

JS: I believe that the large manufacturers of orthopaedic products will welcome smaller companies who can rapidly and competently develop niche, specialty specific products from their inception to completion – including patent protection – and then shop those products among manufacturers. The formation of small, rapidly responsive companies devoted to the development of high quality, clinically relevant products is a concept whose time has come.

AKP: You are in the unique position to evaluate a product or procedure each and every time you perform an operation. Use that opportunity to consider how you might improve that product or procedure for your patient. Then, protect your thoughts and ideas. Write them down in a journal that is signed and witnessed. Share your ideas only under a Nondisclosure Agreement. Consider patent protection.

DD: All ideas are good and should be explored. Keep a journal and record concepts as they present themselves to you. Solutions to problems encountered individually may be solutions worth sharing with the entire orthopaedic community.

OPN: What advice do you have for surgeons who are contemplating developing their own ideas into products, and perhaps starting their own device companies?

JS: I truly believe that surgeons with good product ideas will be best served taking those ideas and preliminary concepts to good small orthopaedic development companies rather than large orthopaedic manufacturers.

If you want to begin a small start-up product development company, get good partners with a high level of business and orthopaedic product design and development expertise.

AKP: To continue to develop products that will adhere to del palma’s motto of: Being a Surgeon Driven Company that is “Advancing Today’s Techniques with Tomorrow’s Technology.”

DD: Continue to work hard and learn all I can.

For more information, contact del palma directly at pguzman@delpalmaortho.com.

Enquiry No 35

ORTHOPAEDIC PRODUCT NEWS

Have the recent economic troubles affected your practice?
We’re interested to know, and plan an update in a future issue of OPN.

Please send your thoughts to:
Julie A. Velizic
Editor, Information Products
ORTHOWORLD
julie@orthoworld.com

ORTHOWORLD
8401 Glengate Road, Suite 18, Cincinnati, OH 45242 \(\approx\) 440.545.2301 \(\approx\) 440.545.2312 \(\approx\) orthoworld.com

34 ORTHOPAEDIC PRODUCT NEWS • March/April 2009
Shaping the Future in Musculoskeletal Stabilization

Multiple-layered polymers in a single thermoformable construct
- protective foam
- thermoformable polymer
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Features
- custom fit
- easy to apply
- adjustable tension
- radiolucent
- waterproof
- reformable
- lightweight

Benefits
- superior comfort
- saves time
- greater stabilization and comfort
- eliminates removal for x-ray
- improved hygiene
- limits waste
- improved comfort
- limits reapplications

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E 651.773.3190
W www.exosmedical.com

Enquiry No 13
**PRODUCT FEATURES**

**UPPER EXTREMITY & POWER TOOLS**

**Sternum Saw Blade**

At American Medical Specialties, we sell cutting tools for powered surgical equipment. Surgical Blades, Burs, K-wires and Pins can be found to fit a variety of handpieces at affordable prices.

AZR-032 is a Sternum Saw Blade similar to the Microaire® ZR-032, Zimmer® 5059-32 and Stryker® 5301-40-32, offered at a price that may help to reduce your Accounts Payable. The blade specs of AZR-032 are blade length 35mm, blade thickness .64mm and blade height 10mm.

American Medical Specialties
Tel: 800-808-2877
www.ammeds.com
Enquiry No 36

**Modular Thumb Implant**

The BioPro® Modular Thumb Implant is a hemispherical interpositional device for treatment of Osteoarthritis and Post-traumatic Arthritis. It is used to replace the symptomatic joint between the first metacarpal and the trapezium. Interpositional arthroplasty offers pain relief and has the benefit of maintaining range of motion and a firm foundation for grip and pinch strength. The modular design of the BioPro implant is intended to minimize complications that have hindered other arthroplasties such as dislocation, material failure and invasive soft tissue reconstructions.

The medial offset head and varus angle of the implant avoid dislocation, plus modularity allows for reproduction of soft tissue tension. The implant is manufactured from cobalt chrome, which has been proven to have excellent biocompatibility. Additionally, the minimally invasive operation does not require any soft tissue releases or sling procedures to maintain functionality. The BioPro Modular Thumb Implant offers simple instrumentation, allowing for easily reproducible results.

BioPro
Tel: 800-252-7707
www.bioproimplants.com
Enquiry No 38

**NBX® Non-Bridging Shoulder Fixation**

FDA clearance has been granted to NuTeck Orthopaedics for the NBX® Shoulder fixator, the second in a family of Non-Bridging External locking devices, earmarked to stabilize peri-articular skeletal fractures. The NBX® Shoulder is designed to offer immediate, temporary or permanent fixation to two-, three- and four-part impacted fractures of the proximal humerus as well as open fractures and nonunions of this anatomy.

The humeral head and neck fragment is reduced and a series of multi-planar, multi-directional small wires are placed through the fixator body to capture each fragment and ensure congruity. Additional pins are placed through the fixator’s arm to hold the repaired head intact within the glenoid. All pins are placed percutaneously, while being held rigid through a unique locking mechanism within the frame.

The NBX® Shoulder fixator is fully radiolucent, light in weight and anatomically conforming. As with all NBX® products, the patient is encouraged to move the shoulder as soon as possible after surgery without fear of the fracture complex dislodging.

NuTeck Orthopaedics
954-779-1400 (phone)
www.nutekortho.com
Enquiry No 37

**MicroAire Carpal Tunnel Release System**

MicroAire Carpal Tunnel Release System (CTRS) is a single-portal, endoscopic release system for treatment of carpal tunnel syndrome. Approaching carpal tunnel release endoscopically allows you to visualize and identify the transverse ligament before a single cut to it is made. The less invasive procedure has been shown to minimize tissue trauma, scarring and pillar pain and cut patient recovery time in half.1,2,3 With over 700,000 successful CTRS procedures performed worldwide, you can approach release of the transverse ligament with precision and confidence.


MicroAire
Tel: 800-722-0822
www.microaire.com
Enquiry No 39
**Ascension® Silicone PIP**

The Ascension® Silicone PIP is designed to replace the proximal interphalangeal (PIP) joint of the hand and enters the market with the smallest pre-flexed silicone PIP joint.

The Ascension Silicone PIP has an anatomic, pre-flexed design reproducing the natural resting position of the PIP joint. It is designed to relieve pain, restore motion and improve cosmetic appearance of the joint. The implant collar and anatomical stems enhance the implant stability and fixation in the medullary canal. When compared to other pre-flexed implants, the Ascension Silicone PIP offers a low-profile dorsal aspect for patient comfort. It is available in six sizes with custom, color-coded instrumentation including cutting broaches and a captured osteotomy guide to facilitate consistent clinical results and decreased operating time.

This new implant system complements our current portfolio of extremities products. We are proud to offer surgeons and patients a full range of implants in both PyroCarbon and Silicone for the MCP and PIP joints.

Key Features of the Ascension Silicone PIP
- Reportedly Smallest Pre-flexed PIP Implant on the Market
- Advanced Hinge Design
- Low Profile Dorsal Collar
- Pre-flexed at 15°
- 6 Anatomical Sizes
- Vertical Cut Guide
- Color-Coded Cutting Broaches

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**Doubleplay™ Suture Implant**

The Doubleplay suture implant is a fully threaded anchor intended to secure tendon to bone. It is manufactured from Bilok® material, a composite of tricalcium phosphate and poly-lactic acid. The threads engage both the cortical and cancellous bone and its innovative “eyeless” design eliminates the risk of eyelet breakage — a feature that is unique to screw-in anchors.

All Doubleplay implants are pre-loaded with 2 strands of MagnumWire®. The sutures, which lie in shallow grooves, run through the body of the hollow anchor and double back around the outside. This protects the sutures and allows them to run freely once the anchor is deployed.

- Osteoconductive composite 30% TCP and 70% PLLA
- Eyeless design for increased strength
- Full threads engage cortex and cancellous bone to maximize pull-out
- Internal driver mechanism supports implant
- 5.0mm and 6.5mm for versatility
- 5.0mm Anchor 260 Newtons pull-out strength
- 6.5mm Anchor 380 Newtons pull-out strength

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_ArthroCare Corporation_

Tel: 800-316-4670

[www.arthrocaresportsmedicine.com](http://www.arthrocaresportsmedicine.com)

Enquiry No 41

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**Please Note:**

In the January/February issue, the Product Feature focus was AAOS & Arthroscopy. We inadvertently titled the section AAOS & Arthroplasty. We apologize for this error, and for any confusion that it may have caused.
Memory Staple

The BioPro® Memory Staple offers an alternative method of fixation for procedures such as arthrodesis, osteotomy or fracture fixation. Available in 17 standard sizes, the Memory Staple’s residual compression makes it more effective than K-wires, screws or plates for many applications.

Manufactured from Nitinol memory alloy, the BioPro Memory Staple uses the patient’s body temperature for activation. Until now, Nitinol staples involved the use of an implant heating device or electrocautery device to activate the staple. The BioPro Memory Staple simplifies the process by fully activating at 98.6°F.

The activation method is complemented by simple, effective instrumentation providing quick, reproducible results. By eliminating the need for an external heating device and providing a simple instrument set, the BioPro Memory Staple offers internal fixation with residual compression while reducing OR time and cost.

BioPro, Inc.
Tel: 800-252-7707
www.bioproimplants.com
Enquiry No 42

tifix™ - Multidirectional Screw-Plate Interlocking

litos/ Corp. from Hamburg, Germany provides tifix™, an interlocking mechanism for osteosynthesis devices. The tifix technology offers safe, variable and easy-to-handle connection of a bone screw with an osteosynthesis plate. The optimized design plus intelligent combinations of pure titanium material from different oxidation levels (grades 1 to 4) allow a controlled cold-forming process between screw head and plate. Individual tilt angles up to 30 degrees between screw and plate are possible.

tifix is available for foot, hand, wrist, femur, tibia, fibula, spine and maxillofacial applications. It has been clinically proven for more than 15 years and provides outstanding benefit and safety in orthopaedics. tifix is protected by multiple patents.

litos/ GmbH&Co. KG
Tel: +49-4073924390
www.litos.com
Enquiry No 43

Scar Rx™ for Scar Management

3-Point Products® introduced Scar Rx™, a single user kit that includes the three steps recommended to relieve adhesions and improve the appearance of scars. Each Scar Rx includes one each:

• SkinSational™ – The gentle massager for comfortable, effective deep tissue massage.
• SacredEarth® Botanicals massage lotion and SacredEarth® Botanicals massage oil – allows user to choose preferred massage medium.
• Gel Mate™ silicone gel sheet – Self-adherent medical grade gel, proven effective at reducing scar discomfort and helping to soften and flatten scars. Easy-to-wear Gel Mate lasts through weeks of wear with proper care.

Scar Rx was developed to present effective scar care in one convenient kit. Scar Rx is available for health care professional purchase and for direct consumer purchase through 3-Point Products.

3-Point Products®, Inc.
Tel: 888-378-7763
www.ohmyscar.com
Enquiry No 44

geneX®....Redefining Bone Repair

geneX® is a new concept in synthetic, fully resorbable bone graft, conferred with a property unique to bone void fillers, Zeta Potential Control (ZPCTM).

Zeta Potential Control (ZPCTM)

The importance of a material’s surface properties in achieving optimal biological activity and bone formation is well documented. geneX’s proprietary process of Zeta Potential Control carefully controls the surface chemistry of the material. This has been shown to harness a number of key proteins that function as regulatory molecules for bone regeneration. By harnessing these proteins, bone cell activity is enhanced, resulting in accelerated bone growth.

geneX is also engineered with SmartPores which produce a developing macroporosity, drawing in cells and nutrient fluids as the graft is absorbed.

Applied as an injectable paste, geneX can be contoured to the surgical site, and sets in situ at body temperature to an exceptional compressive strength.

Biocomposites Inc.
Tel: 910-350-8015
www.biocomposites.com
Enquiry No 45
EVERYONE'S INVITED

Imagine an online collaborative surgeon network where you post difficult cases and receive feedback from Orthopedic thought-leaders and your peers; a world-wide network where you can participate in advancing the science of health care.

Now, over 1400 surgeons from 40 countries have made health care collaboration a reality by joining the growing case-sharing networks www.SpineConnect.com and www.TraumaConnect.com.

NEW collaborative opportunities launched.


Learn more about our collaborative networks and join your peers by going to www.syndicom.com/connect.

Enquiry No 14
In 1998, orthopaedic manufacturers generated some $63 million in revenues from the sales of shoulder replacement products. By 2007, that number exceeded $250 million, an increase of 23 percent per year, making shoulders the fastest growing segment of the U.S. joint replacement market, as illustrated in Exhibit 1.

Exhibit 1: The U.S. Reconstructive Market from 1998 to 2007 Average Annual Growth by Segment

In 1997, we did fewer than 20,000 shoulder replacement procedures. Today’s volume (totals, partials and revisions) exceeds 50,000. Length of stay (LOS) for total shoulder (TSR) patients fell from 3.2 days in 1997 to 2.4 days in 2008. Interestingly, mean hospital charges per total shoulder patient skyrocketed 154 percent from $14,282 in 1997 to more than $36,000 in 2008. The total national “bill” to the system for total shoulder patients rose more than 658 percent during the same timeframe, from $96 billion to more than $700 billion.

At the same time, average physician reimbursement for total shoulder arthroplasty from Medicare (under CPT code 23472) has fallen about two percent (from $1,432 to $1,399). Hospitals, on the other hand, have seen their Medicare reimbursement rise by 32 percent from just over $7,089 in 1997 to more than $9,300 in 2008.

All of these dynamics in shoulders have been mirrored in total hip replacement (THR) and total knee replacement (TKR), as Exhibits 2 and 3 illustrate.

Exhibit 2: Changes in LOS, Charges and the National “Bill” for Total Shoulder, Hip and Knee Replacement 1997 to 2008
Exhibit 3: Changes in Surgeon and Hospital Reimbursement for Total Shoulder, Hip and Knee Replacement 1997 to 2008

Continued on page 42
I can still remember when we all got excited about shoulders in the “early” days of shoulder replacement. At the time, price pressures had come to bear in a big way on the large joint markets, and those markets were highly competitive surgeon-wise. Shoulders, then, became a way for both companies and surgeons to differentiate themselves. Hospitals weren’t fussing about shoulder replacement costs because we didn’t do a lot of volume and reimbursement for doing a shoulder was comparable to what a surgeon (and hospital) received for doing a hip or knee. So, companies “went after” shoulders and the market responded. Healthily.

The remarkable growth in the shoulder market leads us to today’s myriad options for the shoulder surgeon – fracture stems, modular total shoulders with eccentric heads and finned, pegged or keeled glenoids. We’ve got crosslinked poly glenoids, HA-coated and non-coated humeral resurfacing implants and the Arthrosurface HemiCAP for treatment of localized articular cartilage defects of the humeral head. And finally, reverse shoulders joined the mix, with Tornier earning the earliest clearance for a reverse shoulder in the U.S. in 2004. Today, Biomet, DePuy, DJO Surgical, Exactech and Zimmer market reverse shoulders alongside Tornier. Smith & Nephew received clearance for a reverse shoulder last year and plans a limited launch of its Promos system in the U.S. in 2009, with full launch to come in 2010.

By our estimates, DePuy claims the dominant place in the U.S. shoulder market; however, its #1 position is not poured in concrete, particularly given the rapid growth of Tornier’s shoulder franchise over the past few years. Exhibit 4 displays market shares for leading companies in the U.S. shoulder replacement market.

Exhibit 4: The U.S. Shoulder Market in 2007: Market Share by Company

Exhibit 5 summarizes upper extremity joint replacement products currently being marketed in the U.S.

Another IM nail for olecranon fractures, the Arachno-Nail, is available for license from the Mayo Clinic, as is the PEEK-OPTIMA Olecranon and Radial Head Shadow Fixation System. (See www.mayoclinictechnology.com.)

Other interesting upper extremity fracture repair solutions that received FDA’s blessing in 2008 include a wrist fracture implant from Biomet, the F3 Fractured Finger fixator from Hand biomechanics, humeral plate and distal radius screws from Stryker, ITS’ distal humeral plate, ulnar shortening system from Orthopro, volar distal radius plates from Smith & Nephew, Synthes’ olecranon osteotomy nailing system and periarticular proximal humerus plates, Toby’s proximal humerus scaffold fixation system and Zimmer’s polyaxial proximal humerus plates and periarticular locking plates for distal humerus. All these aside, we found a particularly intriguing new fracture repair product in Sonoma Orthopedic’s WristRocket, a minimally-invasive IM device for treating distal radius fractures. (See Exhibit 7.)

Lastly, we’d be remiss if we didn’t mention that Wright Medical acquired the RAYHACK line of wrist reconstruction products currently under development.
Continued from page 42

Exhibit 5: Upper Extremity Joint Replacement Products on The Market in the U.S.: By Company

<table>
<thead>
<tr>
<th>Shoulder</th>
<th>Elbow</th>
<th>Hand/Wrist</th>
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<tbody>
<tr>
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<tr>
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</table>

Exhibit 7: WristRocket from Sonoma Orthopedic Products

systems from Creative Medical Designs. Included in the acquisition are Kienbock’s Radial Shortening Osteotomy, Radial Malunion Distraction Osteotomy and Ulnar Shortening Osteotomy systems. According to Wright, applicable procedures for the system number more than 20,000 annually in the U.S. alone.

So, the upper extremity product arena still attracts buyers and innovators and surgeons. Companies’ interest has not waned either and no wonder, with more than 100,000 arthroplasties, in excess of two million fracture repair procedures of one kind or another and not a lot of scrutiny from the powers that be. Based purely on demographics, we expect this marketplace to continue to provide plentiful opportunities from repair of fingers ravaged and deformed by rheumatoid arthritis to treatment of tennis elbow in young ballplayers. Like most everything else in orthopaedics, upper extremity repair products work in making a difference in patients’ lives. I would imagine that other industries in and out of healthcare wish they could make the same claim.

Shirley A. Engelhardt is President and Founder of ORTHOWORLD Inc., a strategic services firm solely focused in orthopaedics. She is also a Founder and Managing Member of Knowledge Ventures, LLC, an early stage musculoskeletal investment fund. She can be reached at 336-685-5448 or shirley@orthoworld.com.

Enquiry No 46
March 2009

March 2-4
In3 West: Investment in Innovation - Growing your Medical Technology Business through Financing, M&A and Strategic Partnerships
Las Vegas, NV
www.windhover.com

March 7-11
Society of Skeletal Radiology Annual Meeting
Isle of Palms, SC
www.skeletalrad.org

March 11-15
AAOS Continuing Medical Education Course #3302
10th Annual AAOS/AOSSM Sports Medicine Course: From the Sidelines to the Slopes
Steamboat Springs, CO
www.aaos.org

March 16-19
Cowen and Company 29th Annual Health Care Conference
Boston, MA
www.cowen.com

March 20-21
AAOS Continuing Medical Education Course #3303
AAOS/PASE Saint Louis University presents: Novel MIS Techniques for Lumbar Spine Surgery
Saint Louis, MO
www.aaos.org

March 26-27
AAOS Continuing Medical Education Course #3335
AAPA/AAOS presents A PA’s Guide to the Musculoskeletal Galaxy
Fort Worth, TX
www.aaos.org

March 26-28
AAOS Continuing Medical Education Course #3304
AAOS/AOAS Current Techniques in Reconstructive Foot and Ankle Surgery
Rosemont, IL
www.aaos.org

April 2009

April 1-4
European Pediatric Orthopaedic Society 28th Annual Meeting
Lisbon, Portugal
www.epos.efort.org

April 2-4
The British Society For Computer Aided Orthopaedic Surgery 4th Annual Congress
London, England, UK
www.caosuk.com

April 2-5
AAOS Continuing Medical Education Course #3305
9th Annual AAOS/OTA Orthopaedic Trauma Update
Orlando, FL
www.aaos.org

April 3
Annual Meeting: Continuing Education & Professional Development (CEPD) 25th Annual Upper Extremity Update
Toronto, Canada
www.cme.utoronto.ca

April 3-4
AAOS Continuing Medical Education Course #3306
AAOS Focal Cartilage Defect of the Knee Surgical Options
Rosemont, IL
www.aaos.org

April 4-9
7th Annual ISAKOS Congress (International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine)
Osaka, Japan
www.isakos.com

April 17-18
EFORT Instructional Course Advanced – Budapest 2009
Budapest, Hungary
www.efort.org

April 17-20
Uniformed Services University of the Health Sciences (USUHS) 21st Annual International Bethesda Spine Workshop
Bethesda, MD
www.bethesdaspine.com

April 21-23
Annual Meeting - UBC Department of Orthopaedics (UBC), Orthopaedic Update 2009
Vancouver, British Columbia, Canada
www.orthosurgery.ubc.ca

April 22-26
Mid-America Orthopaedics Association Annual Meeting
Amelia Island, FL
www.maoa.org

April 23-25
AAOS Continuing Medical Education Course #3308
AAOS/ASES The Shoulder and Elbow Course: State of the Art
Tucson, AZ
www.aaos.org

April 23-26
AAOS Continuing Medical Education Course #3309
AAOS/AOFAS Fractures of the Pelvis and Acetabulum: Advanced Concepts Details & Improved Techniques
Rosemont, IL
www.aaos.org

April 24-25
AAOS Continuing Medical Education Course #3307
AAOS/FOR Thomas Jefferson University International Symposium on Motion Preservation Technology/Total Knee Replacement and Simulated Hip Replacement
London, England, UK
www.spinearthroplasty.org

April 29-May 1
Spine Arthroplasty Society Ninth Annual Global Symposium on Motion Preservation Technology
London, England, UK
www.spinearthroplasty.org

April 30-May 3
Arthroscopy Association of North America Annual Meeting
San Diego, CA
www.aana.org
## May 2009

- **May 2-7**: 77th American Association of Neurological Surgeons Annual Meeting  
  San Diego, CA  
  www.aans.org

- **May 3-6**: American Association of Orthopaedic Executives Annual Conference  
  Austin, TX  
  bones.affiniscape.com

- **May 4-8**: International Society for the Study of the Lumbar Spine Annual Meeting  
  Miami, FL  
  www.issls.org

- **May 7-9**: Sports Medicine & the NFL: A Sideline Perspective  
  San Francisco, CA  
  www.sportsmed.org

- **May 13-15**: Banner for Orthopaedic Care: Quality Innovation Summit  
  Cleveland Clinic  
  Cleveland Heights, OH  
  www.ccfcme.org/OrthoRheumQuality09

- **May 13-17**: Association of Bone and Joint Surgeons  
  Maui, HI  
  www.abjs.org

- **May 16-20**: National Association of Orthopaedic Nurses 29th Annual Congress: Uniting the World of Orthopaedics  
  Tampa, FL  
  www.orthonurse.org

- **May 17-20**: Current Concepts in Joint Replacement Spring Meeting  
  Las Vegas, NV  
  www.ccjr.com

- **May 23-26**: 8th World Congress of the International Cartilage Repair Society  
  Miami, FL  
  www.cartilage.org

## June 2009

- **June 3-6**: European Federation of National Associations of Orthopaedics & Traumatology - 10th EFORT Congress  
  Vienna, Austria  
  www.efort.org

- **June 10-13**: American Orthopaedic Association 122nd Annual Meeting  
  Bonita Springs, FL  
  www.aoassn.org

- **June 17-20**: 26th Annual San Diego Shoulder Arthroscopy, Arthroplasty and Fracture Course  
  San Diego, CA  
  www.shoulder.com

- **June 17-20**: Eastern Orthopaedic Association Annual Meeting  
  Paradise Island, Bahamas  
  www.eoa-assn.org

- **June 23-26**: AOSpine North America Global Spine Congress 2009  
  San Francisco, CA  
  www.globalspinecongress.org

- **June 24-25**: OMTEC 2009: The 8th Annual Orthopaedic Manufacturing & Technology Exposition and Conference  
  Donald E. Stephens Convention Center  
  Rosemont, IL  
  www.orthosupplier.com

## July 2009

- **July 9-12**: American Orthopaedic Society for Sports Medicine Annual Meeting  
  Keystone, CO  
  www.sportsmed.org

- **July 15-18**: Southern Orthopaedic Association 2009 Annual Meeting  
  Amelia Island, FL  
  www.soassn.org

- **July 16-18**: 16th IMAST Meeting - International Meeting on Advanced Spinal Techniques  
  Vienna, Austria  
  www.imastonline.org

- **July 29-August 1**: Western Orthopaedic Association Annual Meeting  
  Seattle, WA  
  www.woa-assn.org

## August 2009

- **August 12-15**: SIGN Conference on Treatment of Difficult Fractures Around the World  
  Richland, WA  
  www.sign-post.org

## September 2009

- **September 3-5**: American Society for Surgery of the Hand 64th Annual Meeting  
  San Francisco, CA  
  www.assh.org

- **September 4-5**: Sinai Hospital of Baltimore and St. Vincent Medical Center Hip Joint Preservation and Resurfacing Arthroplasty Course  
  Baltimore, MD  
  www.hipresurfacingcourse.com
September 5
Sinai Hospital of Baltimore; Rubin Institute for Advanced Orthopedics
External Fixation of the Foot and Ankle
Baltimore, MD
www.deformitycourse.com

September 6-9
Sinai Hospital of Baltimore; Rubin Institute for Advanced Orthopedics
19th Annual Baltimore Limb Deformity Course
Baltimore, MD
www.deformitycourse.com

September 7-12
22nd European Conference on Biomaterials - Annual Meeting of the European Society for Biomaterials
Lausanne, Switzerland
www.esb2009.org

September 9-11
Rodman & Renshaw Annual Global Investment Conference
New York, NY
www.rodmannandrenshaw.com

September 10-11
Sinai Hospital of Baltimore; Rubin Institute for Advanced Orthopedics
Osteomyelitis and Segmental Bone Defects
Baltimore, MD
www.deformitycourse.com

October 2-4
Knee Society Interim Meeting
Denver, CO
www.kneesociety.org

October 8-10
Orthopaedic Trauma Association Annual Meeting - 25th Anniversary
San Diego, CA
www.ota.org

November 2009

November 10-14
North American Spine Society 24th Annual Scientific Meeting
San Francisco, CA
www.spine.org

November 27-29
British Society for Computer Aided Orthopaedic Surgery (CAOS UK) Annual Meeting
London, United Kingdom
www.caosuk.com
OMTEC 2009
The 5th Annual Orthopaedic Manufacturing & Technology Exposition and Conference
June 24-25, 2009
Donald E. Stephens
Convention Center
Rosemont, Illinois

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Enquiry No 17
AAOS Annual Meeting: Getting Back to Basics

As I write this, the start of the 2009 American Academy of Orthopaedic Surgeons’ annual meeting is a mere week away. And if my clients’ and their colleagues’ estimates are to be believed, attendance at this meeting will be down over 50 percent. Hyperbole, paranoia, hysteria? Perhaps. But if attendance is down even a double digit percentage over years gone by, we will have concrete evidence that this new order of compliance, for better or worse, has changed the industry forever.

Here is what we know for sure. First, the meeting is being held in “sin city.” If I am a government regulator, I am in hog heaven thinking that not only do I get to go to Las Vegas on assignment, but the odds of finding several violations of the AdvaMed Code of Ethics on Interactions with Health Care Professionals are way better than the odds I will get at a craps table at the Venetian. Second, all five of the orthopedic companies that are operating under a deferred or non-prosecution agreement have sent their sales field express directives regarding appropriate and inappropriate (read: stuff that will get you FIRED) behavior, which directives those companies rightfully expect will be followed. And last but not least, surgeons are more disillusioned than ever about the level of scrutiny this business has undergone in the last two years. That’s what we know. But what does all of that mean?

For starters, any company, including sales agencies and their physician clients, that is stupid enough to break the rules that we all know are going to be enforced at AAOS this year deserves to be punished. Seriously, could we get more of a wake-up call from the government and from the companies that have lived with the government in their backyard for so very long now? Whether you agree with the various prohibitions or not (the Restated AdvaMed Code has already started raising eyebrows), it could not be more obvious that the new law of the land requires 100 percent compliance and has zero tolerance for anything less.

Second, there is no question that this year’s meeting will be about one thing and one thing only: orthopaedics. Not that it hasn’t been in the past, but the only acceptable behavior this year will be visiting booths and attending presentations. It’s not all bad, if you think about it…wasn’t that why the meeting was originally organized?

And lastly, what is so awful about buying your own dinner and keeping yourself entertained after hours? Don’t forget, the prohibitions on socializing only apply to your sales reps and other company personnel. If you want to hit the town, feel free! Find a buddy from medical school who you haven’t seen in years and get yourself in the kind of trouble that those “what happens in Vegas, stays in Vegas” commercials were talking about. Just pay your own way. These tough economic times are hard on everybody, but I am going to wager a guess that you still have enough disposable cash to hit a slot machine or two.

Unfortunately, by the time you read this, you either will have heeded my advice or not.

Now that everyone reading this article is completely annoyed with me, let me say this: I am reporting the facts, not offering an opinion. What is my opinion, you may ask? We are going too far, plain and simple. A Restated AdvaMed Code of Ethics that disallows branded pens and pads of paper because they are potential inducements misses the mark in my personal estimation. But, the real inquiry to make is: how did we get here? AdvaMed didn’t follow PhrMAs lead for nothing. Abuses in this industry ran rampant throughout the ’90s and the early years of this decade. Don’t believe me; just read the Deferred and Non-Prosecution Agreements meted out against the Big Five and the myriad qui tam and other lawsuits currently pending against orthopaedic device manufacturers, their sales fields and the physician customers they serve. We were greedy, sloppy and plain old arrogant about our place in the world relative to governmental oversight (please notice that I included myself in the group of offenders) and we have no one to blame but ourselves.

Which brings the question, what can we do about it? I am still working on that one. Regaining the government’s trust (and that of the general public, to a certain extent) won’t be easy. But it needs to happen. So, for a while, it is back to basics. Back to the days when your sales rep wasn’t your primary social outlet or your key to a great golf game. Back to the days when doctors

continued on page 49
didn’t expect companies to subsidize their second homes; instead, they simply expected excellent product offerings and singular customer support.

Being friends with your sales rep isn’t just good manners. It’s good medicine. The closer you and your rep are outside of the OR, the more effective you are as a team inside the OR. Those of us in the industry have understood that for years. But the appearance of impropriety has simply gotten overwhelming. And in light of the fact that there needed to be a fix of some sort, the government inevitably threw out the baby with the bath water. So, while you and I both know that hanging out with your rep (and having him buy a drink or two and a decent dinner) isn’t how you choose the products you use, the presumption is out there that it is. So in the words of Snoopy, Be Cool. I trust that you behaved this AAOS, and that you will at all future industry meetings. Don’t put your reps or other company personnel in an awkward spot asking for things you know are not allowed. Abide by these new rules and don’t shoot the messenger (meaning your sales rep or me). And remember, if we want the benefit of the doubt with the government, we are going to have to earn it.

The Law Offices of Teresa Ford, PC (www.tfordlaw.com), located in Houston, Texas, specialize in healthcare and medical device issues. Areas of expertise include healthcare compliance program structuring and training, as well as advising individual physician clients. Founding partner Teresa Ford spent many years in the medical-legal arena, most recently as senior counsel for Sulzer Medica USA Inc. She can be reached at 832-251-9595 or tford@tfordlaw.com.
Registries as Useful Clinical Research Tools in the Study of Orthopaedic Treatments

Introduction
Randomized, controlled clinical trials (RCTs) represent the ideal model for comparing two or more medical treatments. However, a typical RCT can take years and cost millions of dollars to complete. Furthermore, RCTs are difficult to conduct when the treatments under consideration are medical devices which typically require surgical implantation (McLeod, 1996).

As an alternative, registries are useful because they promote careful collection and storage of patient data in anticipation of future research purposes. When RCTs are not feasible, well-planned retrospective studies based on registries may provide useful information regarding the relative benefits of competing orthopaedic procedures and devices.

What is an Orthopaedic Registry?
A broad definition of an orthopaedic registry is an organized collection of data on patient demographics, diagnoses, procedures, implant information, outcomes and adverse events over some period of follow-up. A registry may be set up at the physician, clinic or national level. For example, an orthopaedic surgeon, with patient consent, may collect pre-surgery and follow-up data on her patients over a number of years. A similar kind of data collection may be instituted at a hospital, so that any patient receiving an implant there would contribute to the registry.

National orthopaedic registries have been established successfully in a number of countries, including Sweden, Finland, Norway, Canada, Switzerland and Australia, among others. Perhaps the most famous of these is the Swedish Hip Registry, which has been in use since the late 1970s. Each registry is typically specialized to a particular type of orthopaedic surgery (e.g., total knee or total hip arthroplasty), although the inclusion of a general class of procedures (e.g., any arthroplasty) is possible.

Why are Orthopaedic Registries Needed?
As pointed out by Maloney (2001), orthopaedic registries can provide timely information on both the safety and patient outcomes for particular procedures or implants. Knowing that an implant has been failing at an alarming rate can be useful to both doctors and patients. Potential problems with devices can be detected quickly, since an existing registry can be continuously monitored. Without a registry, it could take years to recognize problems happening in a physician’s practice or with currently implanted devices.

A recent article in the New York Times (July 29, 2008) reported on a specific instance in which a component of a certain total hip replacement was found to have higher than expected revision rates, but only after 1,000 patients had received the device. The article goes on to suggest that a U.S. national registry may have sped the process of having the implant recalled and the problem corrected, thereby reducing the number of patients exposed to a faulty device.

Examples of Useful Registries
A search of the orthopaedic literature reveals a number of valuable uses of registries at both the institutional and national level. Also, these registries have been used to study not only specific types of orthopaedic surgery, but also a range of injuries and conditions of interest to orthopaedic surgeons.

Recent studies published in Journal of Bone and Joint Surgery illustrate the use of the Finnish Arthroplasty Registry, the construction of which began in 1980. However, registration of total joint replacements has only been required since 1996. Jamsen et al. (2009) reported on risk factors for infection based on more than 43,000 cases of total knee arthroplasty. In an analysis based on nearly 51,000 cases between 1980 and 2004, Makela et al. (2008) commented on the long-term survival of total hip replacements performed for osteoarthritis in patients over 55 years old. Sheng et al. (2006) reviewed the survival of revision total knee arthroplasties, with the analysis including over 2,600 cases from 1990 through 2002.

Reports of registry-based studies from Norway and Australia can be found in articles by Hallan et al. (2007) and Williamson et al. (2009). Hallan et al. studied the occurrences of aseptic loosening and stem revision in more than 11,500 uncemented femoral stems from the Norwegian Arthroplasty Register. In Williamson et al. (2009), 1,290 adult patients treated for various orthopaedic injuries and registered in the Victorian Orthopaedic Trauma Outcomes Registry (Australia) were evaluated for pain and health status six months after the initial trauma.

Individual institutions and hospitals have published interesting uses of registries. Dudley et al. (2008) used a community-based registry in the HealthEast hospital system in St. continued on page 51
continued from page 50

Paul, Minnesota, to study outcomes associated with unicompartmental knee arthroplasty revisions. These results were based on over 7,500 knee arthroplasties performed between 1991 and 2005.

In an investigation performed at the Mayo Clinic in Rochester, Minnesota, a review of their total joint registry found that over 17,700 total knee arthroplasties have been performed from 1981 to 2004 (Galat, 2009). Fifty-nine knees found to have early wound complications requiring surgery were studied, and subsequent treatments and risk factors were studied.

Two similar articles involving hospital-specific registries were reported in the Journal of Pediatric Orthopaedics in 2007. Kirkpatrick et al. (2007) studied injuries resulting from all-terrain vehicle (ATV) accidents involving children, as reported in the trauma registry at the Oklahoma University Medical Center. Their retrospective study included 73 children under the age of 16 years who had been injured in an ATV accident since 2001. Kute et al. (2007) reported on 238 children with ATV-related injuries treated at a level one trauma center in Kentucky over an 11-year period.

Conclusion

Registries can be used to benefit the orthopaedic community, in particular, in the retrospective evaluation of the relative benefits of orthopaedic therapies. Aside from allowing quick access to current trends in patient outcomes and adverse events, registries could permit higher-quality retrospective studies to evaluate long-term performance of implanted devices. Study quality could increase as well, since problematic issues of obtaining patient consent, collecting accurate data and maintaining high follow-up rates could be resolved on a systematic basis as patients are treated and included in the registry. Furthermore, a well-planned registry should promote increased care in data collection and recordkeeping at the center/country housing the registry.

A larger question that continues to be raised is whether national orthopaedic joint registries are needed in the U.S. Based on previous successful studies and convincing arguments, (Maloney, 2001, is a good example), there is evidence and reasoning that such registries are needed and could prove extremely useful.

However, the feasibility of instituting any kind of national joint registry, especially in a country as large as the U.S., is certainly in doubt, although a pilot effort is currently underway to assess the viability of implementing a national pediatric musculoskeletal trauma outcomes registry (Vitale et al, 2006). The cost, complexity and effort of building a national registry would be considerable and would require multi-institution cooperation.

REFERENCES


R. Jason Schroeder, Ph.D. is the Biostatistician at InMotion Musculoskeletal Institute. He also holds adjunct faculty appointments at both Christian Brothers University and the University of Memphis. He can be reached at jschroeder@inmotionmemphis.org.

Enquiry No 48
More than ten years ago, Dr. Scott and Sally Harrison founded CURE International with one specific goal: heal the 100 million children suffering from physical disabilities in the developing world. Surgical care of this neglected and often forgotten group of children was not a priority for any other organization. Dr. Harrison, an orthopaedic surgeon and entrepreneur, saw the tremendous needs of disabled children firsthand while on several medical mission trips to Africa and was determined to deliver the healing these children so desperately needed.

In 1998, CURE opened its first hospital in Kenya. It was Africa’s first pediatric orthopaedic teaching hospital for physically disabled children. Today, CURE International operates ten specialty hospitals in nine countries and plans to open two more over the next 24 months. These hospitals focus on treating children with orthopaedic conditions and in some locations also perform neurosurgery and plastic surgery for repair of cleft lips and palates. They have become essential components of the medical care system in these countries.

Over CURE’s ten-year history, its hospitals have served more than 800,000 patients and its international team of medical experts has performed life-changing surgery on more than 55,000 children. CURE International is now the world’s largest provider of pediatric specialty care in the developing world.

Making medical care more easily accessible is an important facet of CURE International’s operating strategy. To do this, CURE places an emphasis on the training of national medical personnel. The presence of orthopaedic medical specialists in the developing world is virtually nonexistent in many countries. In Malawi, it is estimated the ratio of Malawians to orthopaedic surgeons is 2.3 million to one; in Kenya, this figure is one million to one. In comparison, there are approximately 16,000 Americans for every orthopaedic surgeon in the U.S.

Even more distressing is that, when medical professionals do receive specialized training, they often leave their home countries to practice in Western Europe, the U.S. and Canada. Reasons for this commonly termed “brain drain” include the lack of training and career advancement opportunities and financial incentives in the developing world.

For instance, it is estimated that 90 percent of African doctors trained in America never return to their home country.

CURE’s presence in the developing world is helping to reverse this trend. By building specialty surgical centers, CURE International offers national surgeons more career opportunities and more chances to experience advanced training in the most modern health care techniques. The organization has established programs for orthopaedics, neurology, general medicine and nursing at its hospitals. CURE’s emphasis on these training programs makes it unique in its overall approach to delivering medical care in the developing world.

In the last decade, CURE International has provided specialized orthopaedics training, including short courses, to more than

continued on page 54
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Enquiry No 20
The program has produced more than 50 OCOs who are working throughout the country. One of these is James Msiska.

“As an orthopaedic clinical officer who has gone through the orthopaedic training program, I feel it is good,” James said. “We are the backbone of orthopaedic patient management as we do not have enough orthopaedic surgeons (in Malawi).”

The Malawi Ministry of Health recently recognized the importance of the program by contributing $85,000 to help fund the next class of OCOs.

CURE also provides important in-country training to nationals through its innovative CURE Clubfoot Worldwide initiative, which establishes programs in developing countries. An integral component of each program is the training of orthopaedic surgeons and para-medical professionals in the Ponseti Method of clubfoot treatment, proper use of the Pirani diagnostic scoring system and proper application of treatment protocols for maximum reach and effectiveness in resource-poor settings. To date, this program has trained and equipped more than 250 medical and counseling professionals in ten countries over the last two years.

An additional benefit of the focus on training for CURE is the international medical experts that its hospitals attract. A number of orthopaedic professionals from the U.S., the U.K. and other countries have spent time at CURE hospitals, where they often teach classes and serve as mentors to national medical professionals.

“Over the past three years, a number of top-quality visiting professors have greatly added to the resident education and quality of services we offer,” said Dr. Scott Nelson, the full-time Medical Director at CURE’s hospital in the Dominican Republic.

“This has given the opportunity for the residents to work and develop relationships with surgeons from other programs in the United States.”

As CURE continues to provide life-changing healing to disabled children in the developing world, its commitment to training will remain just as strong, said Dr. Scott Harrison.

“Because of our training programs, we’ve not only created new opportunities for orthopaedic surgeons in the developing world, but dramatically improved the quality and availability of care for disabled children,” he explained. “We are committed to expanding these programs to other countries. We want CURE’s presence in these countries to have a lasting impact on the health care system and those who desperately need treatment.”

Lisa Wolf is vice president of communications and donor relations for CURE International. She can be reached at lwoolf@cureinternational.org.

Enquiry No 49

As a non-profit organization, CURE International relies on the support of generous individuals to operate its hospitals and conduct its training programs. You can help us change the face of medical care in the developing world by sponsoring the training of a fellow orthopaedic professional at one of our hospitals. If you would be interested in finding out more about this opportunity, please send an email to info@cureinternational.org or call 717-730-6706. To learn more about CURE International, please visit www.cureinternational.org.
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Enquiry No 22