



THE SIGN POST

NEWSLETTER OF THE SURGICAL IMPLANT GENERATION NETWORK
APRIL 2002

2950 George Washington Way • Richland, WA 99352 • TEL: (509) 371-1107
FAX: (509) 371-1316 • EMAIL: signcom@sign-post.org • WEB SITE: www.sign-post.org
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Our Mission: To get the injured out of bed

Imagine for a moment that you have sustained a serious leg fracture. Although unpleasant, by virtue of living in America you would have access to treatment options that would get you walking again.

Now imagine that you sustained a leg fracture, and that you are one of the one billion people in the world who live on less than \$1 a day. You would not be able to afford treatment. Your options would be limited to staying in bed permanently or having the leg amputated. A fracture that could be treated would debilitate you for the remainder of your life. You would no longer be able work and provide for your family and children. They would have to provide for you.

SIGN exists to meet this need. By providing surgical implants and training at no cost to surgeons in the developing world, we enable surgeons to provide superior fracture care to the poor. In all we do, our goal is to heal the injured poor and get them out of bed.

THE SIGN IMPLANT: X-ray images of a femur fracture before and after treatment with the SIGN nail. The nail passes through the central canal of the bone, aligning the bone so it can heal properly and rapidly.

THE STATE OF SIGN: THREE YEARS OF HEALING

Lewis G. Zirkle, Jr., M.D., President and Founder of SIGN

It is hard to believe that SIGN is only 3 years old. In 1999, Acumed gave us a jumpstart by manufacturing our first SIGN nail system. Over the subsequent year, I visited sites in Indonesia, Vietnam, and Thailand to introduce surgeons to the SIGN system. Dr. David Moehring started a SIGN project in Katmandu, Nepal. SIGN was well received in all of our first project locations. We used feedback and clinical reports from site project managers to evaluate SIGN's effectiveness and improve our products. Just three years later, SIGN now has 30 established projects around the world (see map, below left).



Elver and Dr. Zirkle in Honduras

The year 2001 was very successful for SIGN. We manufactured 6,000 SIGN nails. Over 1,000 fractures were healed with the SIGN treatment worldwide. SIGN instrument sets and implants were distributed all over the world. We developed a new retrograde femur nail (inserted upward through the knee) and manufactured new instruments for insertion and extraction. We obtained FDA approval for our tibia and retrograde nails, and prepared the patent application for our system. In December 2001 SIGN expanded into India, where there are 700,000 tibia fractures each year. Six new projects were started in India, with more to come.

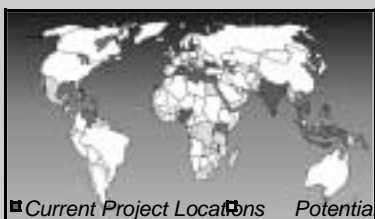
The employees at our factory in Richland are extraordinary. Under the guidance of Jeanne Dillner, our SIGN staff has developed into a cohesive unit that operates effectively. We continue to critically evaluate and improve the manufacturing, materials, and design of our products, and then fit these improvements into a product schedule to supply the increasing demand. Several corporations have given SIGN valuable assistance, including Acumed, Battelle, Framatome, Babcock Services, and The Digital Image.

In the future, we must turn our efforts toward fundraising so SIGN can bring its proven healing to more people in need. We seek financial support from individual donors and corporations. For \$25,000, a corporate sponsor can fund the establishment of a new SIGN project at a hospital. The hospital receives a starter SIGN instrument set and the continued supply of implants for three years. The starter instrument set alone has a market value of over \$50,000. Suggestions on fundraising would be greatly appreciated.

SIGN continues to stress developing relationships with in-country surgeons, teaching them, and then equipping them with SIGN implants and instruments to treat fractures. This is indeed a global effort.

HEALING IN 2001

- 20 Projects Established
- 200 Surgeons Trained
- 1,000 Fractures Healed
- Lives Improved in Incalculable Ways



Currently there are 30 established SIGN projects in countries throughout the world, including India, Vietnam, Nepal, Bangladesh, Indonesia, Thailand, Nigeria, Malawi, Honduras, and Venezuela. We are expanding to many new locations to bring superior fracture treatment to more people in need.

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PROJECT LOCATION: SOUTH VIETNAM

SIGN currently has 30 projects worldwide, and we are expanding. With each newsletter, we will focus on one geographic region in order to provide an in-depth view of the impact that SIGN is having.



Population: 79,939,014
GDP per capita: \$1,950
Life Expectancy: 69.5 yr

VIETNAM: SIGN'S FIRST DESTINATION

The name Vietnam is repeatedly heard around SIGN. The Center for Traumatology & Orthopaedics (CTO; above right) in Ho Chi Minh City was the first location of a SIGN project, which was established in 1999. Subsequently, SIGN has spread to eight major hospitals throughout Vietnam. In 2001, 69 fractures were treated with the SIGN treatment at CTO alone, raising the standard of treatment for all fractures.

The widespread use of motorbikes in Vietnam (far right) make the population vulnerable to severe fractures. As in many developing countries, the incidence of severe fractures in Vietnam is rapidly increasing due to road traffic accidents as motorized vehicle use increases. Traffic accidents will soon be the third leading cause of death worldwide, and over 80% of severe fractures occur in developing countries. To prevent these fractures from permanently debilitating Vietnamese patients, SIGN provides the resources that Vietnamese surgeons need to provide quality fracture treatment.



Center for Traumatology & Orthopaedics (CTO), Ho Chi Minh City.



The CTO waiting room. CTO treats 300,000 patients annually.



Traffic: Opportunities for Injury

SKILLED SURGEONS... AND A NEED FOR RESOURCES

With a public health expenditure averaging only \$81 per capita (compared with \$4,180 in the U.S.), Vietnam's health care system is forced to make do with a shortage of resources. For example, waiting rooms are typically very crowded (above), and patients are often placed two or more to a bed (left).

The lack of resources serves to continually challenge and refine the skills of Vietnamese surgeons. SIGN has found that the surgical ability of Vietnamese surgeons is equivalent to and in some ways exceeds that of their Western counterparts. Indeed, SIGN has significantly benefited from the ingenuity of Vietnamese surgeons. Their experience and expertise with the SIGN implant system has provided us with valuable feedback on how to improve our products.



PROJECT MANAGERS: PARTNERS IN HEALING

Every project location has a project manager who reports the results of SIGN implant cases back to SIGN. This communication has provided SIGN with valuable feedback for improving our products, and has helped to build close relationships between SIGN and Vietnamese surgeons.

Vietnamese surgeons were the first to use the SIGN tibia nail to treat femur fractures (see x-rays at right), prompting SIGN to develop a retrograde femur nail that is implanted through the knee. SIGN is currently designing an antegrade femur nail that will be implanted down through the hip.

Vietnamese surgeons have been to eager to learn the SIGN system. In 2001, 100 surgeons attended a SIGN conference led by Dr. Zirkle at Cho Ray Hospital in Ho Chi Minh City. Many of them traveled throughout the night to attend the conference. As Vietnamese surgeons have become more familiar with the SIGN system, they now teach one another.

We at SIGN are grateful for our partners in healing in Vietnam.



Dr. Quang



Dr. Tuan



Pre-operation and post-operation x-rays of a femur fracture treated with a SIGN nail by Dr. Tuan.



THE REWARD: TO HEAL A PATIENT

In a motorcycle accident, this 22-year-old Vietnamese woman fractured her femur in two places and her tibia in one place in her left leg. Her knee was "floating" between the fractures. With limited treatment options because of poverty, she was originally slated for amputation, a procedure that would have made it nearly impossible for her to work or find a spouse. She was one of the earliest patients to have a SIGN tibia nail placed into her femur by Vietnamese surgeons. A SIGN nail was also placed through the tibia fracture. Six weeks after receiving SIGN implants, she is standing on her injured leg, avoiding a lifetime of disability.



In a severe traffic accident in the city of Binh Duong, Tran suffered multiple fractures in her femur and tibia. Due to bone loss, only a small piece of bone at the end of her tibia remained. SIGN nails were placed up through her femur and down through her tibia. The tibia nail had to be anchored in her foot for stability because of bone loss. Dr. Tuan, a Vietnamese surgeon, bone grafted the area where there was severe bone loss, and transplanted a flap of skin from her shoulder to cover up the large open wound in her lower leg. One year later, Dr. Tuan sent this picture to SIGN, along with the fantastic news that: "One year later, Tran has a short leg but she can walk now. She and her family are satisfied with the result."

Although SIGN's nails are used for adults, children benefit when an injured father or mother quickly returns to work after receiving the SIGN treatment.



SIGN PROJECT REPORT: CAN THO

By Dr. John Giesen, Coeur d'Alene, ID, orthopaedic surgeon

I spent 2 weeks in Vietnam during winter 2001, splitting time between Ho Chi Minh City and Can Tho. My first impression of Ho Chi Minh City was that there are at least 500 motorcycles to every automobile and that the traffic is horrendous.



The morning after I arrived I went to the Orthopaedic ward of the large Cho Ray Hospital and I was taken on rounds. I saw numerous challenging fracture cases as well as post-op patients and cases. The volume of fracture work was very impressive. In most cases the quality of their work based on x-rays appeared to be quite good. They showed me all of their SIGN nail cases they had done recently. They also have many external fixators in place. The next day I went to the operating room and helped a young orthopaedist with an anterior cruciate substitution. In the same room they were doing a SIGN nail on a distal femur fracture.

After 3 days, I traveled to Can Tho, a city of 200,000 in the Mekong River Delta. I returned to the same hospital I worked at in 1966 (as a military surgeon). The doctors took me on rounds and we lined up three nice SIGN cases to do the next day. They were two tibial fractures and one distal femur. I did 3 or 4 more cases in the next week. They went well and the doctors started to get enthusiastic about the SIGN equipment. The last day I was going to be with them, I gave a lecture with the SIGN equipment and after that I felt that the Vietnamese doctors were making the equipment and procedure their own.

The doctors and the staff at the hospital were extremely friendly and appreciative of what we were doing for them. We should have another person with experience with SIGN nails get back to Can Tho as soon as possible and reinforce the correct use of the equipment. I feel that the introduction of the SIGN nail will greatly upgrade the trauma care in Can Tho.

I want to thank Dr. Zirkle and everybody else who helped me make this trip.

VIEW FROM THE BOARD

*By Randy Huebner, Executive Vice-President, Acumed
Vice-President, SIGN Board of Directors*

My interest in SIGN began with Lew [Zirkle]. When I first met him, he described his goal of dramatically improving the level of orthopedic care in a long list of needy countries. He wanted surgeons to be able to count on a steady supply of fracture products that matched their training and were designed to suit some of the unique problems that exist in many of these countries. Unlike almost every nonprofit that I know of SIGN actually builds and delivers a product to the people who need it. This was one of those rare opportunities where my skills matched one piece of this great project that Lew had envisioned. My interest continues each time that I see a x-ray of a broken leg or a picture of a person who has been helped by SIGN.

The most significant thing about SIGN to me is simply the number of people who are treated by these implants. With much of the groundwork in place, SIGN is well positioned to dramatically ex-

pand the number of patients who are helped through SIGN training and products. SIGN is very much like Acumed was when we started. Like SIGN, Acumed began with a low budget, dedicated people and clear goals. Because we make similar products we have in common many of the same problems and successes. The fact that SIGN is nonprofit really doesn't make much of a difference on a day to day basis. Like Acumed, their basic goal is to make a good product as efficiently as possible and deliver it to as many patients as possible.

SIGN is full of sincere, dedicated people who have made tremendous progress building a great organization and I am privileged to be a part of it. In the future I want to continue to work on any of those pieces that Lew feels will best help SIGN.

To me, one of the most exciting long term goals of SIGN is to transfer the product technology to these countries so that they can eventually become self sufficient in producing and developing products for their own people.



Every day, SIGN is able to help fracture victims walk again because of the generosity of our donors and volunteers, and the commitment of our staff



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Lewis G. Zirkle, Sr.

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April 30—May 2:
Health & Safety Expo
TRAC, Pasco

June 1:
SIGN Charity Golf Tournament
Columbia Point, Richland

For more information, contact SIGN

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Doug Donnelly: Regulatory Affairs
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Nadia Davis: Bookkeeping
Lainie McElroy: Communications



Douglas Laity: Fundraising
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Gary Davis: Finish Processing
Dule Mehic: Design / Programming
Mark Wilson: Quality Control

*Special thanks to former staff members who were instrumental to SIGN's development:
Steve Critchlow, Scott Johnson, Chris Smith, Dan Wodrich*