Richland's SIGN Creates Implants to Heal Fractures Around the World

by Kristi Phil – Tri-City Herald

The minds behind SIGN Fracture Care International of Richland found a better way to treat fractures of the tibia and other bones.

But instead of cashing in on the stainless steel nails it manufactures, the Richland company gives much of what it makes away to hospitals in developing countries.

SIGN's nonprofit status and mission make it unique among Tri-City manufacturers. Giving the implants away is simply the right thing to do, said Dr. Lewis Zirkle, the founder and president.

The company had its beginnings in Zirkle's garage, but became a nonprofit 16 years ago and employs 35 people.

SIGN surgeons around the world repaired fractured bones in about 18,000 operations using the nonprofit's tools and nails last year, said CEO Jeanne Dillner. The implants have been used in about 150,000 surgeries since 1999.

All of the nails and screws, and most of the tools that make the surgeries possible, are made at the nonprofit's Richland facility. It has expanded its manufacturing capacity — the goal is to make 27,000 nails this year, said Richard Grizzell, operations manager.

Those nails are needed not only to create sets for surgeons newly trained to use SIGN's equipment, but also to restock the supplies available to surgeons at partner hospitals.

"They should always have a good selection available," he said.

A SIGN nail starts out as a solid, 12-foot long bar of stainless steel. The steel is an implantable grade, made with a specific tensile strength and metal mix.

The nails can be made in under five minutes, much faster than the 15 to 16 minutes it used to take before SIGN upgraded to a new machine. The software and the additional tools that can be loaded into the new screw machine help cut that time down, Grizzell said.

Workers place the 12-foot bars into a feeder attached to the machine, and inspect the nails once they are finished to make sure they meet SIGN's specifications.

The nails are then ultrasonically cleaned, buffed, cleaned again and bent.

A hydraulic press is used to bend the nails to the angle needed for them to work for the implant surgery, Grizzell said. The machine holds the nail at that angle for some time, so when the machine releases it, the angle remains.

For a while, a volunteer would hand crank a machine to press the nails into the right shape, Grizzell said. But about four years ago, SIGN was able to add the hydraulic press and eliminate the need for human muscle strength.

The nails are then smoothed and laser marked with SIGN's logo, the size of the nail and the job number.

Two machines are dedicated to making the sizes of screws used to hold the implantable nails in place. They are programmed to make the specific screws needed, which are then cleaned and smoothed.

It takes four minutes on average to make a screw, Grizzell said. They could not be made by hand.

Human eyes and an electronic optical vision system are used to inspect finished nails and screws. Once through inspection, the nails and screws go through a final cleaning. After that, no human hands touch them while they are packaged, inventoried and shipped.

SIGN tries to keep more than 6,000 nails and about 15,000 screws on hand to fill orders from partner hospitals, Grizzell said. During a recent week, some of the outgoing supplies and equipment was headed for hospitals in Zimbabwe, Afghanistan, Haiti, Vietnam, Pakistan and Uganda.

When finished, the nails look fairly simple, a solid piece of metal with holes and slots, bent into a slight angle. The diameter ranges from 8 millimeters to 12, in 1-millimeter increments. Lengths range from 220 millimeters up to 420, in 20-millimeter increments.

One of the most commonly used nails is 9 millimeters in diameter and 320 millimeters long, Grizzell said.

SIGN also makes a pediatric nail. It has a smaller diameter and one interlocking slot farther down from the tip of the nail to avoid impacting the growth area of the bone, Dillner said.

The nail wedges inside the canal of the bone, holding the bone in the position it needs to be in so the fracture can heal, Grizzell said.

The nails do need to be removed from children once healing is complete, but can be left in adults, he said. Adults often want them removed for cultural reasons.

SIGN also makes most of the surgical instruments needed to perform the surgery, including the slot finder that allows surgeons to do the implant surgery without the use of an X-ray machine, Grizzell said. That tool is used to find the slot in the nail so that the screw can be placed through the slot and into the bone.

Hospitals will take an X-ray before surgery and several days afterward, but they don't need to have a real-time X-ray machine available during the surgery, Zirkle said.

There are some products needed for the surgeries that SIGN does outsource.

For-profit companies had tried to do what Zirkle and others managed to accomplish with SIGN, Dillner said. They were lucky that what they tried ended up working as intended.

"We figured out how to solve the problem, and instead of making a profit on it, we just give it away," Dillner said.

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