Imagine developing and manufacturing innovative, life-saving products—and then finding out that you can’t get them to your customers. That’s precisely the situation that OsteoSymbionics®—a Cleveland-based company that designs and makes patient-specific craniofacial implants—found itself in several years ago.

In fact, the company was facing a dilemma that threatened its very survival. Before surgeons could use OsteoSymbionics’ signature CLEARSHIELD® cranial implant in surgery, the device first had to be sterilized. For years, hospitals had relied upon an on-site sterilization process utilizing ethylene oxide (EO) to accomplish that task, explains OsteoSymbionics CEO Dorothy Baunach. But when the chemical was recognized as a known carcinogen back in 1994, its use in hospital sterilization began to wane. Hospitals either significantly reduced their reliance on the EO process, or began to discontinue the use of ethylene oxide sterilizers completely because of the residual risks of working with, and disposing of, such a dangerous chemical.

“We knew our company was on the line unless we found another sterilization method,” Baunach explains. Without a reliable method to sterilize the CLEARSHIELD method was a life-saver for our company.”

—OSTEOSYMBIONICS CEO DOROTHY BAUNACH
devices in the hospital, it was getting increasingly difficult for the company to get its implants to patients in a timely manner. This was critical because patients who need CLEARSHIELD implants often have a compressed time window for surgery, so alternative, off-site sterilization methods with long lead times just wouldn’t work.

Then in early 2013, an executive at OsteoSymbionics heard about Cantel Medical Corp.’s REVOX® Sterilization Solutions process, the first new sterilization technology in the medical industry in nearly two decades. REVOX Sterilization uses a Peracetic Acid (PAA)-based vaporized sterilant to perform sterilization at room temperature, between 18 and 30˚C.

FEWER RESIDUALS, MORE MATERIAL COMPATIBILITY

The REVOX sterilization method addressed OsteoSymbionics’ unique and specific needs. Because CLEARSHIELD implants are heat-sensitive, they could not be sterilized using that method. Chemical processes were not an option either, as the product could not retain its physical or bio-compatible characteristics with such sterilization methods. That’s what made the REVOX method such an attractive option for the company, says Baunach.

Mason Schwartz, REVOX Operations Manager and Co-Inventor, says other experiments similar to their work with OsteoSymbionics are underway in the fields of donor tissue processing, porcine valves, and biological—anywhere “sterility versus viability” are long-standing balancing acts. Because REVOX acts at much lower temperatures than other sterilization technologies, Schwartz points out that it provides manufacturers with

In May 2014, the FDA granted OsteoSymbionics 510(k) approval for sterilization using the REVOX method.
much greater flexibility when it comes to material compatibility.

**GAINING FDA APPROVAL**

Still, the company realized the biggest hurdle to adding REVOX to the CLEARSHIELD production process would involve getting FDA approval for this new sterilization method. “Initially we thought we could seek special 510(k) approval,” she says. This route is typically the fastest path to FDA approval, taking 90 days or less. It requires little or no data submission, and is designed to fast-track approval for a device that is essentially the same as one that already exists or where only minor packaging changes are made.

However, the FDA viewed REVOX’s new sterilization process as a significant innovation that warranted full testing and data submission, explains Schwartz. “Because the FDA wanted a full approval, which would push the approval back longer than expected, we made sure our data package to the FDA was incredibly thorough,” he says. “It normally takes nine months to complete the full process, but thanks to our due diligence we were able to get approval a month earlier than normal.” In May 2014, the FDA granted OsteoSymbionics 510(k) clearance for sterilization.

That effort proved critically important for CLEARSHIELD’s long-term survival, says Baunach. “Our sales were really eroding at that point so we needed something fairly quickly to replace the old EO sterilization method,” she explains. “The testing REVOX did was just first class. If they weren’t so meticulous I don’t know that we would have gotten the approval when we did. Even though we’re a small company, the entire REVOX team provided excellent customer service and was incredibly responsive to our needs throughout the entire process.”

**ENABLING GREATER RESPONSIVENESS**

But what most appealed to Baunach and her team was that the REVOX sterilization process enabled her company to deliver its CLEARSHIELD device to hospitals pre-sterilized, rather than relying on the hospital to sterilize. Today, the majority of OsteoSymbionics’ CLEARSHIELD implants are shipped to the REVOX Sterilization Minneapolis headquarters where they are sterilized within 24 hours. From there, they are overnighted back to the OsteoSymbionics facility in Cleveland where they are then sent on to the hospital in time for surgery. The goal, says Baunach, is to eventually have a REVOX sterilization chamber installed at the Cleveland site, thereby eliminating the need to ship the devices back and forth, speeding in-line processing of the implants.

In the meantime, Baunach says the company has regained lost customers and has signed on new ones as well. “The REVOX sterilization method was a life-saver for our company,” she says. “It’s nice once again to focus on what our company does best and have peace of mind that the sterilization part of the equation is being handled so professionally.”

> For more information check out www.revoxsterilization.com