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LDR SPINE USA, INC.: LEADING THE WAY

Offering the Only Individually Packaged & Sterilized Spine Products

LDR Spine (Austin, TX), a total spine solution company, is leading the way in the spinal implant industry as the only company to offer sterile spinal implant systems. Their unique product line, which includes pre-sterilized fusion devices, including pedicle screws and rods, will ensure the simple and reliable management of spinal implants in and out of the operating room. All LDR spinal implant products are delivered to the hospital individually packaged in a double blister sterile packaging, with sterilization control stickers. This unique LDR sterile packaging ensures that implants are delivered to the surgical field in their original condition. "This makes a lot of sense," says Stephen H. Hochschuler, MD, Chairman and Co-founder of Texas Back Institute, and Clinical Instructor, Department of Orthopedics, University of Texas Southwestern Medical School (Plano, TX.). "LDR Spine sterile packaged implants are a great idea because they eliminate the need to sterilize a multitude of implants or question the sterility of a product. There is no need to worry about implants that have been trialed, removed, and improperly cleaned, and that may have tissue contaminants left behind."

This practice has many obvious advantages and it can be seen as a natural step–one that was taken by the total-joint industry many years ago. There was a time when total hips were all provided non-sterile, but there is not an orthopedic surgeon practicing in the United States today who would find it acceptable to have hip devices provided non-sterile. Although other specialties have made the move to exclusive use of sterile implants, the spine industry has not yet made the changeover. Other spine companies may offer their new products sterile, but they are neglecting to change their existing implants and fusion systems. According to John K. Stokes, MD, Austin Brain & Spine (Austin, TX), "We've been using LDR Spine products for approximately 6 months. With their individually wrapped implants, you know they've been sterilized to the manufacturer's specifications. There is no chance of screws that have been exposed to other patients being placed back in the set. From a patient safety standpoint, it's certainly a superior technique. There are cases in which you may, for example, use a rod that you bend and then decide against implanting. Frequently, it will find its way back into a set, although it may have been damaged by the bending." With all of the obvious reasons why it should, why hasn't the spine industry made the change to exclusive use of non-sterile systems? One answer may be related to the cost. Dr. Stokes believes that "other companies' resistance to providing implants packaged this way is really a cost issue. I think it would be a significant cost to those manufacturers to take the existing sets out of the hospital and repackage them individually." With postoperative infections a serious and costly complication of orthopedic surgery, the matter of cost is not a sufficient explanation.

LDR Spine sterile packaged products mitigate the risk borne by reprocessed spinal implants. One of the most significant risk factors regarding reuse is the potential for infection, especially in invasive surgical procedures. According to one study of 850 spine patients, the infection rate was measured to be in excess of 2.5% (1). The risk of infection has been shown to increase as much as sevenfold with use of invasive devices (2). For more than two decades, it has been a standard practice of U.S. hospitals to reprocess and reuse spinal medical devices that have been labeled for "single use." Although this has generally been considered to be a safe practice, for every study that demonstrates the safety of reuse, there is another study that shows the detrimental effects reprocessing can have on patients (3). Evidence has shown that some single-use devices (SUDs) cannot be safely reprocessed and that hospital procedures may not be validated for sterilization of reused products. Furthermore, the FDA, device manufacturers, and third-party reprocessors generally agree that many types of SUDs cannot be safely cleaned and sterilized (4). For those devices that can be reprocessed, there are some that are impossible to clean and sterilize successfully (5). According to Daniel L. Peterson, MD, Austin Brain & Spine, "Every LDR implant that you're using is sterile from the factory and has not gone through numerous cycles of sterilization and washing. A major consideration in implant surgery is with implants that are provided non-sterile. These are implants that are not designed to come out. During a typical procedure, you destabilize someone's spine and then you put in screws and bone graft to try to stabilize it. It takes a period of time for a fusion to set, so if you get an infection in that environment you can really be in trouble."

Dr. Hochschuler finds that these sterile packaged implants also optimize management of inventory and simplify the process. "Hospitals have what they need and can use it right off of the shelf." Dr. Peterson agrees. "Inventory control for the hospital is simpler and surgeons are more likely to implant the correct size implant as the sets can't get jumbled as to sizes and appropriate tray positions." Additionally, each LDR implant offers absolute traceability–from the initial manufacturing step to the final implantation. By providing products in sterile packaging, Dr. Peterson adds, "This is a more reliable and easier method of tracking the implant in case of recall or other issues."

LDR Medical was founded on the premise that there were still many unsolved issues in spine surgery. LDR pledges to work collaboratively with surgeons to create new implants, instrumentation, and techniques to help make spine surgery better, more consistent, and easier for surgeons, and to provide an even better quality of life for patients.

For more information concerning LDR Spine, call 1-512-344-3333 or visit the company's Web site at www.ldrspine.com.

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