



SpineTune™ TL

PEDICLE SCREW SYSTEM

Reduced hospital costs

- Procedures using LDR pedicle screws require fewer trays to clean and sterilize. At some facilities this represents cost savings of \$100/tray.
- No hospital resources are spent managing or storing non-sterile implant inventory.
- The reduction of infection risks may result in fewer costly patient complications.

Full implant traceability

- Product labeling and lot identification enhance the ability to track every implant to an individual patient.
- Implant chart labels facilitate accurate hospital documentation of implant utilization.

Product integrity

- Validated sterile packaging protects each implant during transportation and storage.
- Every patient receives new implants - never subjected to mechanical damage from previous use in the operating environment.
- Each implant box includes the FDA required Instructions for Use (IFU).

Guaranteed sterility

- Sterile-packaged implants are never exposed to other patients, blood, or contaminants in the O.R., and are not subject to variations and failures of localized handling and cleaning.
- LDR uses controlled, validated Gamma irradiation sterilization at a minimum dose of 25kGy, per the ISO 11137 standard.
- In addition to being sterilized per a validated process, each implant box has two radiation verification dots and sealed packaging for point-of-use confirmation of sterility.

Sterile-packaged Pedicle Screws

The question is not
“Why?” but “Why Not?”

With some studies¹ reporting infection rates as high as 3% for posterior lumbar fusion surgery, if you have the option to use pre-packaged sterile implants, why wouldn't you?

LDR has a passion for innovation in design and development of spinal solutions. But our passion does not stop there. We believe that patients, surgeons, and hospitals deserve safe implants. This drives our dedication to preserve product quality through the cleaning, packaging, and delivery of our implants, as well.

While other manufacturers remain content to deliver non-sterile implants in a sterilization tray, relying on the hospital for sterility control, LDR takes full responsibility for the quality and traceability of each implant from the initial stages of manufacturing all the way to the final implantation in the patient.

Since its inception in 2000, LDR has provided every one of its pedicle screws in sterile packaging. It is a commitment with clear benefits for patients, surgeons, and hospitals.

¹ Smith J, Shaffrey C, Sansur C, et al. Rates of infection following spine surgery based on 108,419 procedures: A Report from the Scoliosis Research Society Morbidity and Mortality Committee. Spine Journal, ISSN: 1529-9430, Vol: 9, Issue: 10, Date: 2009-11-02, Page: 725.