INSTRUCTIONS LEAFLET
SpineTune™ TL Spinal System Non-Sterile (LDR Spine – USA)

0459

CONTRAINDICATIONS

• Any material or material disorder which would result in an unacceptable risk of failure, fixation or complications in post-operative use
• Basic bone composition by disease, infection or prior fixation which cannot provide adequate support and fixation to the implant.
• Osteoporosis, osteopenia, or local bone demineralization
• Basic bone destruction by disease, infection or prior fixation which cannot provide adequate support and fixation to the implant.
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INDICATIONS FOR USE

• Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life.
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In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially

The above list of side effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

Stabilization Procedures

• Only FDA cleared wraps (or other FDA-cleared accessory), validated to maintain sterility after processing, are to be used.
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Material

The SpineTune™ TL Spinal System consists of self-drilling, internally-threaded instruments, stainless steel constructs (spine rods, connectors, screws, hooks, etc.), and decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and sterilization of the medical devices shall be performed using validated methods. Adverse events and/or reactions due to infection or contaminated medical devices shall be documented.

Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or

The SpineTune™ TL Spinal System is made of surgical implants titanium alloy Ti6Al4V ELI, which complies with ASTM

SpineTune™ TL Spinal System should not be used in conjunction with components from any other manufacturer’s spinal systems.

Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to

The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation

The devices are also not recommended for use in conjunction with any other medical implant. The use of these implants is contraindicated in the presence of any condition that would make the patient unsuitable for implantation, including infections or conditions that would prevent appropriate healing and stability.

The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation

The above list of side effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

Precautions

The SpineTune™ TL Spinal System is intended for use in the treatment of deformities of the spine, particularly scoliosis and kyphosis, in adults and children. It is contraindicated for use in patients who have a history of allergy to any components of the system.