INSTRUCTIONS FOR USE
TRUE SPINAL FIXATION SYSTEM

PURPOSE
The True Spinal Fixation System ("True") provides the instruments and implants necessary to provide spinal column stabilization.

DEVICE DESCRIPTION
The True Spinal Fixation System consists of implants which can be rigidly locked to provide spinal column stabilization. The True Spinal Fixation System screws, connectors, and rods are manufactured from medical grade titanium alloy (Ti 6Al-4V ELI ASTM F-136). The True Spinal Fixation System instruments are manufactured from IXEF PARA GS-1022 GY/5/1.

USE OF SYMBOLS
Manufacturers table of standard symbols
CE mark (in compliance with 93/42/EEC Directive on medical devices)
For single use only
See instructions for use
Manufactured By
Catalogue Number
Expiration Date

INDICATIONS
The True Spinal Fixation System is intended for posterior, non-cervical (T1-S1) pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spine tumor, pseudarthrosis and failed previous fusion.

Risks
Potential risks identified with the use of spinal fixation devices include the items listed above in the Potential Adverse Events section.

CONTRAINdications
Contraindications and relative contraindications include, but are not limited to:
- Fractures
- Morbid obesity
- Active alcoholism or drug abuse
- Active tobacco usage
- Significant osteopenia and/or osteoporosis
- Lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

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POTENTIAL ADVERSE EVENTS AND RISKS
In addition to the inherent risks with spine surgery, potential adverse events for surgery using the True Spinal Fixation System include, but are not limited to:
- Delayed union, malunion or non-union (pseudarthrosis)
- Implant malpositioning
- Bone loss or decreased bone density
- Significant hemorrhage
- Wound or systemic infection
- Pain, discomfort or irritation due to the presence of the surgical implants
- Skin perforation, breakdown, irritation, fibrosis, pressure sores or inadequate tissue coverage over the implants
- Nerve or spinal cord damage due to improper positioning or migration of the surgical implants
- Necrosis of bone
- Failure to achieve or maintain spinal alignment
- Failure to improve pain or worsened pain following surgery
- Adjacent vertebral level arthritis

These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spine tumor, pseudarthrosis and failed previous fusion.

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Potential risks identified with the use of spinal fixation devices include the items listed above in the Potential Adverse Events section.

Implant Strength and Bone Healing
The True Spinal Fixation System is intended to act as a load-bearing device to provide stabilization of vertebrae within an area of fusion of the thoracolumbosacral region until bone healing can occur. The True Spinal Fixation System should not be used in situations where the anterior elements (vertebral bodies, discs and anterior ligamentous structures) are not capable of bearing physiologic loads.

MR Compatibility
The True Spinal Fixation System should be used only as a dual rod system only.

PreeaCUTIONS
Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the surgical technique for use of the True Spinal Fixation system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Single Use Only
True is provided as single use, sterile packaged implants and instruments. All packages should be inspected prior to use. Do not use if expiration date has passed. If the packaging appears compromised, do not use. If the implants or instruments appear damaged, do not use. Never re-implant an explanted medical device.

Disposable Instruments
True contains single use, disposable, sterile packaged instruments. Instruments should not be reprocessed or reused and are for single use only. All packages should be inspected prior to use. Do not use if expiration date has passed. If the packaging appears compromised, do not use. If the instruments appear damaged, do not use.

Care and Handling
If rod contouring is needed, avoid sharp bends, notches or rounded bending which may adversely affect the strength and integrity of the rod. Avoid scratching or otherwise damaging any implant surface which could adversely affect the strength or mechanical performance of the implant, leading to premature failure.

Surgical Technique
The implantation of the True Spinal Fixation System should be performed only by a qualified and experienced spine surgeon with recognized surgical technique and experience. The surgeon should be familiar with the surgical technique and instruments and show evidence of competence in all areas of spine surgery. The surgeon should consider the levels of implantation, patient weight, and the biology of the bone and soft tissue to determine the feasibility of the fusion.

WARNING
Thesafetyandeffectivenessofpedelescrew脊柱内系统havebeenestablishedonlyforspinalconditionswithsignificantmechanicalinstabilityordeformitydemandingfusionwithininstrumentation.