Transforaminal Lumbar Intervertebral Fusion Cage

Implants

TLIF PEEK cage - 13x32mm - h 7	LFC-002PK3207
TLIF PEEK cage - 13x32mm - h 9	LFC-002PK3209
TLIF PEEK cage - 13x32mm - h 11	LFC-002PK3211
TLIF PEEK cage - 13x32mm - h 13	LFC-002PK3213

Complete instrument set	LFC-00000002S
zonnbiete instrument set	LI C-000000023

INTENDED USE

Properly used, the Sintea Plustek TLIF Lite spinal stabilization system is indicated to develop a solid interbody fusion of the lumbar spine. It is recommended in case of degenerative discopathy, pseudoarthrosis, spondylolysthesis. Supplemental posterior fixation is needed.

CONTRAINDICATIONS

The contraindications of Sintea Plustek TLIF Lite spinal stabilization system are analogous to those of similar products currently available, and include, but are not limited to:

ABSOLUTE:

- Infections in the active state
- Allergy to the metal components
- Patients who are either unwilling or unable to follow instructions

RELATIVE:

- Metastasis
- Trauma
- Serious muscular, neurological or vascular disease
- Fever or leucocytosis
- Pregnancy, except in the case of treatment for unstable vertebral fractures
- Signs of flogosys at the planned site of the implant
- Inadequate soft tissue coverage at the implant site
- High level osteoporosis

If the implant of a Sintea Plustek TLIF Lite spinal stabilization system is considered the best solution for the patient, and if the patient presents one or more of the above contraindications, it is essential that the patient is informed of the possible negative consequences that might hinder the success of the procedure.

Sintea Plustek S.r.I.

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Sintea Plustek LLC

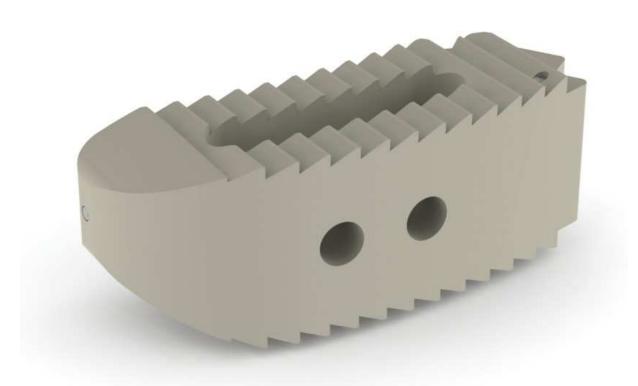
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TLIF Lite

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COMPONENTS

LUMBAR FUSION CAGE

The TLIF Lite Transforaminal Lumbar Intervertebral System is indicated for intervertebral body fusion in the lumbosacral region. The device comes in four different sizes (7mm, 9mm, 11mm and 13mm), in order to ensure an optimal fit to the patient anatomy. For each size one lordosis profile is available (7°), allowing to restore the spine physiologic curvature.

The cages are characterized by a particular "banana-like" shape: the rounded lateral extremity improves the insertion in the intervertebral space. The central cavity allows for a large grafting space, thus enhancing and speeding up the fusion process and restoring the anatomical spine continuity.

The primary stability of the implant is assured by superficial teeth that allow the gripping on the endplates and prevent the migration of the device from the interbody space.

The cages are manufactured of biocompatible PEEK polymer; due to the radiolucency of the material, three radiographic markers in titanium alloy allow complete visualization of the device during intraand post-operative care.

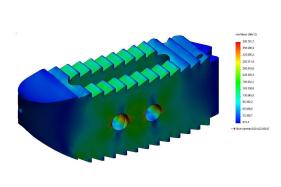
The TLIF Lite spacer is implanted using a transforaminal approach and is intended to be used singly with supplemental fixation.

All the components of the system are in accordance with the Directive 93/42 CEE.

TECHNOLOGY AND INNOVATION







DESIGN AND ENGINEERING

The elements of the TLIF Lite system were designed using the standard methods of structural analysis and continuum mechanics. The results were also validated by means of the Finite Element Method, in order to establish the optimum sizing in relation to device requirements and user specifications, and by static and fatigue tests, which reproduced the most critical load conditions.

INNOVATIVE ASPECTS

The TLIF Lite cage has been designed to ensure an optimal anterior support.

The rounded shape of the implant, which resembles a banana, allows for an easy insertion and rotation in in the intervertebral space.

Moreover, the lordotic configuration allows a perfect adaption to the anatomy.

The terminal part of the cage presents a suitable milling and a threaded hole to allow a firmly grip with the implant holder.

FEATURES

ROUNDED SHAPE FOR OPTIMAL INSERTION

WIDE OPENINGS

7° LORDOSIS

STERILE PACKAGING

EXCELLENT PRIMARY STABILITY

PEEK

