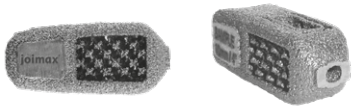
Instructions for Use (USA)
EndoLIF® Implants

These Instructions for Use apply to the following implants of the EndoLIF® product family:

EndoLIF® On-Cage
ELON643008 – ELON643014
ELON643508 – ELON643514

EndoLIF® Delta-Cage
ELDL6425084 – ELDL6425124
ELDL6425088 – ELDL6425128



EndoLIF® DoubleWedge-Cage
ELDW64271012 – ELDW64271612
ELDW64271018 – ELDW64271618
ELDW64321012 – ELDW64321612
ELDW64321018 – ELDW64321618

PRODUCT DESCRIPTION AND PURPOSE

EndoLIF® cages are implants used to stabilize the intervertebral space and support osseous fusion of vertebral bodies of the lumbar spine. They can be implanted via a posterior or posterolateral approach in an open or minimally invasive procedure. EndoLIF® implants should always be combined with a dorsal fixation system.
The EndoLIF® Delta-Cage should always be implanted in pairs.
EndoLIF® cages are made from a titanium alloy (Ti6Al4V ELI) and are available in various shapes and sizes. The anatomical shape of the cages consists of a rigid frame with an open diamond cell structure inside.
Selecting a suitable size and shape of implant and choice of surgical procedure for each patient is of crucial importance to the success of the procedure.

⚠ SAFETY INSTRUCTIONS

Read the Instructions for Use/Product Usage Guide carefully and entirely prior to surgery. The products must be stored in a cool, dry area and protected from direct light. The implants are packaged individually in a sterile environment and can, therefore, be used immediately. Sterility is guaranteed as long as the packaging is not damaged. Further information can be found on the packaging label. The products must not be used if there is any damage to the product or packaging. The implants must be handled as specified in the product usage guide in order to ensure sterility. The implants must not be used after the expiration date. The products are sterilized with gamma radiation. They are intended for single use only and may not be resterilized. In case of unauthorized resterilization and subsequent reuse, joimax® refers to the following: If the single-use products are reused, no assurance is given that they will function as intended nor that they will be sterile and free from contamination. If, contrary to these instructions, products intended for single use are reprocessed and resterilized, this releases the manufacturer from any product liability. Biological hazards can arise following the use of medical devices.

SCOPE OF APPLICATION / USER GROUP

The implants are used in sterile operating rooms. Detailed information regarding the procedure, the use of the implants, and the instruments required can be found in the corresponding product usage guide. EndoLIF® cages must be used only with instruments recommended or supplied by joimax®. The products mentioned above must only be used by a physician familiar with their application and in accordance with current medical standards. joimax® provides an extensive training program for this purpose.

INDICATIONS

EndoLIF® Cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). EndoLIF® Cages are to be used with autogenous bone and implanted via a posterior or posterolateral approach. They are to be used with supplemental FDA cleared fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an EndoLIF® Cage.

CONTRAINDICATIONS

- Fractures
- Tumors
- Active infections
- Allergies to titanium or titanium alloys
- Fever or leukocytosis
- Pregnancy
- Mental illness
- Morbid obesity
- Insufficient soft tissue coverage at the operation site
- Rapidly progressive osteoarthritis, bone resorption, osteopenia, poor bone quality or osteoporosis
- Cases that require various components made from different metals
- Patients unable to follow the post-operative instructions
- These implants must not be used for pediatric cases, or while the patient is still growing
- Any situation that excludes the potentially positive progression of a spinal implantation, e.g. tumors
- Congenital abnormalities
- Unexplained increase in erythrocyte sedimentation rate
- Significant shift to the left in the differential blood count
- Abuse of tablets, drugs, tobacco, or alcohol (these can affect the ossification process)
- All not listed indications

INTERACTIONS / INCOMPATIBILITIES

The EndoLIF® Implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of joimax® EndoLIF® Implants in the MR environment is unknown. Scanning a patient, who has this device, may result in patient injury. The cages are made from Ti6Al4V ELI and must not be combined with metal implants other than titanium or titanium alloys. There are no other known interactions/incompatibilities.

POSSIBLE COMPLICATIONS

In addition to the general risks associated with a spinal operation, the following complications may arise during or after surgery. This list does not claim to be exhaustive.
- Malpositioning of the implant
- Loosening of the implant
- Discoloration of breakage of the implant
- Foreign body reaction caused by the implant (e.g. development of a tumor, autoimmune disease, and/or poor healing)

- Altered mobility in the operated segment
- Adjacent segment disease
- Subsidence of the implant
- Migration of the implant
- Change in the natural curve of the spine in this segment
- Partial loss of the height correction achieved through the surgery
- No ingrowth of the implant, no fusion of the adjacent vertebral body
- Pseudarthrosis
- Compression of adjacent tissue and organs during the procedure
- Superficial or deep infections and infl ammatory conditions, e.g. discitis, arachnoiditis
- Changes at adjacent levels, e.g. herniated disc, adjacent fractures
- Neural deficits, e.g. radiculopathies, dural injuries, dural cysts
- Neurovascular complications, e.g. hemorrhage, hematoma, wound healing complications
- Venous thrombosis, pulmonary embolism and cardiac arrest,
- Deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism
- Gastro-intestinal diseases, urinary tract disorders, sexual dysfunction
- Respiratory failure
- Changes in psychological behavior
- Inability to return to normal everyday activities
- Death

Note: Some of the aforementioned complications may require surgical reintervention.

WARNINGS AND PRECAUTIONS

joimax® is not responsible for complications and risks arising from:

- Incorrect diagnosis
- Wrong choice of implant size
- Choice of a non-recommended surgical technique
- Selection of instruments that are not recommended by joimax® for this implant
- Limitations of the treatment methods
- Inadequate hygiene
- Incorrect handling, e.g. storage before, during, and after the operation
- Contact with chemicals
- Not using a dorsal fixation system

STORAGE

EndoLIF® cages must be stored in a cool and dry environment in their original packaging until use and protected from both direct sunlight and extreme temperatures.

DISPOSAL

The use and disposal of medical products must take place in accordance with statutory regulations and recognized methods.

WARRANTY RESTRICTIONS

joimax® guarantees to manufacture the products with utmost care.
joimax® GmbH issues the legally specified warranty period with regard to the function of instruments. The validity period of this warranty is limited to claims made within the specified warranty period after the instrument's purchase date, with reference to repairs if required and with specification of the invoice number. This warranty only encompasses defects not caused by normal wear and tear, misuse, wrong handling, no or incorrect preparation or force majeure. This warranty excludes wearing parts. This is the only valid warranty and replaces all other issued warranty declarations. joimax® component sets as well as individual products are compatible with each other. Before using individual joimax® products/sets with other products, the user must ensure the user-specific compatibility of individual products. We recommend introductory training and regular attendance at training events. We are available for any further required information. joimax® has no influence on the application of the product, on the diagnosis of the patient and handling of the product outside of joimax®. joimax® cannot guarantee good results nor the complication-free application of the products. joimax® employees are not entitled to change the previously mentioned conditions, extend liability or enter additional product related obligations. joimax® reserves the right to make product changes. This document contains information protected by copyright and property law and may not be copied in full or in parts thereof or transferred to a further medium in any form, without express written permission from joimax® GmbH. Distribution to third parties is prohibited. The products and names used here may be the registered brands of joimax® or other companies. Patents are granted or pending. joimax® GmbH is grateful for any information regarding possible errors and obscurities in these Instructions for Use.

CE CONFORMITY MARKING

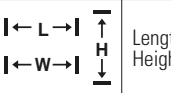
The CE marking confirms product compliance with the Medical Device Directive 93/42/EEC and the German Medical Devices Act (MPG).

EMERGENCY NUMBER

Please notify us of any events according to MPG § 29 or § 2 of the German Medical Device Safety Plan Ordinance under the following telephone number:
for the US 949-859-3472 (24-hour availability)
for all other countries +49 (0) 721 255 14-999 (24-hour availability).

Thank you for your support!

SYMBOLS

	Caution, please refer to the accompanying documents!	℞ only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	Observe the instructions for use.	STERILE R	Gamma radiation sterilization
	Use before		Length (L), Width (W), Height (H)
LOT	Batch number		Angulation
REF	Order number		Keep away from sunlight
	Do not use if packaging is damaged		Keep dry
	Not for reuse		Manufacturer
	Do not resterilize	QTY 1 EA	Packaging unit
	Not made with natural latex rubber		

REF IFUONCAUS

℞ only

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joimax® GmbH
Amalienbadstraße 41
RaumFabrik 61
76227 Karlsruhe, Germany

Phone: +49 (0) 721 255 14-0
Fax: +49 (0) 721 255 14-920
E-Mail: info@joimax.com
Net: www.joimax.com

In USA distributed by

joimax®, Inc.
140 Technology Drive, Suite 150
Irvine, CA 92618, USA

Phone: +1 949-859-3472
Fax: +1 949-859-3473
E-Mail: info@joimaxusa.com
Net: www.joimax.com