L-VARLOCK
Adjustable interbody lumbar cage
INSTRUCTIONS FOR USE

NON STERILE

CE 0499
2000

1. PURPOSE OF MEDICAL DEVICE

The L-VARLOCK cage makes it possible to perform lumbar interbody fusion by posterior approach with restoration of disc height and of physiological lordosis.

2. INDICATIONS

- Degenerative disorders: symptomatic advanced disc disease, herniated disc, degenerative spondylolisthesis
- Spondylolisthesis by symptomatic isthmic lysis
- Spinal deformity (scoliosis, sagittal and/or frontal spinal imbalance)
- Potentially unstable spinal stenosis and foraminal stenosis
- Traumatology: in case there is a need to treat a fracture

L-VARLOCK cages must be systematically implanted by pairs and used in combination with posterior osteosynthesis.

3. CONTRA-INDICATIONS

General:
- tumours
- a physiological or psychological condition of a patient contra-indicating the operation (pregnancy, anatomical particular aspect, etc.)
- progressive or recent infectious process

Specific:
- allergy to component material of the implant: titanium (and alloys)
- comminuted fracture of the vertebral body,
- lesions in diseased bone (osteoporosis, etc.) due to trauma or not

4. DESCRIPTION OF MATERIALS PROVIDED

Implants are provided for single use, provided non-sterile, either in a box with trial implants and instruments or in a unit packaging comprised of the following:

- 1 hermetically sealed packet with a tamper-resistant label
- 1 identification label on the packet
- 1 instruction leaflet per dispatch

L-VARLOCK implants are expansive intervertebral cages. This expansion of the cage, partly anterior, is achieved by an adjustment screw (posterior approach), resulting in rearward movement of a screw. Such opening makes it possible to restore the desired lordosis.

Cages come in two shapes: standard or narrow. They have teeth on the sides in contact with vertebral plates. On the posterior aspect of the cage, a dovetail joint makes it possible to fit the grasping tool/impactor.

A wide range of implants is available, combining the following:

- Several heights, to open foramina,
- Several widths and lengths, to ensure perfect stability of the osteosynthesised levels while respecting anatomical constraints.
- An adjustable opening preoperatively, which makes it possible to gradually restore physiological lordosis and to lock the cage into the interbody space.
- A wide graft compartment for good bony fusion.
- A metallic mass distributed homogeneously in order to decrease artefacts in radiographic examinations (MRI is possible).
- Reduced operating time through use of a simple well adapted instrument enabling precise, rapid implantation.

The implant is identified by its name, mentioned on the label of its packaging and by its reference mentioned on the label of its packaging and engraved on the implant itself.

4 copies per size are provided.

TECHNICAL CHARACTERISTICS:
- Materials: all implants are made of titanium alloy Ti-6Al-4V ELI in accordance with medical standard ISO 5832-3 and ASTM F136.
- 8 heights according to width (10 mm and 13 mm) and height (8 mm, 9 mm, 11 mm and 13 mm).
- The 10 mm width cage has a length of 22 mm.
- The 13 mm width cage has a length of 27 mm.
- Screw adjustment for amplitude of lordosis:
  - Narrow cages: between 0° and 24.5°
  - Standard cages: between 0° and 13°

5. MATERIALS NECESSARY FOR PLACEMENT OF THE IMPLANT

The kit containing L-VARLOCK instruments necessary for placement of implants is referenced in the catalogue of KISCO International products.

6. STORAGE CONDITIONS

Implants must be stored at room temperature in their original packaging or in the box provided for this purpose by KISCO International:


Keep dry


Store away from light and sunlight

In the absence of deterioration of the packaging, and in compliance with conditions for storage, cleaning and sterilisation, implants can be used without limit of duration.

7. PRECAUTIONS/WARNINGS

a) General considerations

- Implants are delivered NON-STERILE. They are planned to be cleaned and sterilised according to instructions in paragraph 8.
- Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. **The implant must be discarded.** Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such reuse may also result in infection in the patient.
- Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. **Knowledge and experience in spinal surgery are pre-requisites.**
- Furthermore, appropriate selection of patients, as well as the patient's cooperation, greatly affect results.
- Implants must be placed on a tray for use.

b) Warning for the surgeon and medical staff

It is important to give the patient the following information before the procedure, in order to ensure success of the surgical implantation:

- Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished, alcoholic, obese, or patients with muscle weakness or nerve paralysis.
- To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
- The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
- Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
- These implants do not present any known risk of interference with other medical equipment.
- Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.

8. PREPARATION OF DEVICES

a) Cleaning/decontamination

- Whether they come directly from their original packaging or from the tray for use, implants must be cleaned and decontaminated in conformity with legislation in force prior to sterilisation.
- KISCO International recommends cleaning the non-sterile devices by performing manual cleaning combined with automatic cleaning, using a heat disinfector which complies with standard EN ISO 15883-1, used with an alkaline cleaning product with

pH ≤ 10. Validation has been performed with the "VARIO-TD" programme and the "neodisher® MediClean" cleaning product:
- Prewashing: < 45 °C, 2 min
- Washing: 55 °C, 5 min
- Neutralisation: tap water temperature, 2 min
- Rinsing: with cold tap water, 2 min
- Heat disinfection: demineralised water, 90 °C, 5 min
- Drying: 22 min

Other cleaning methods are described in the guide "Recommendations for maintenance, cleaning and sterilisation of medical devices"*.

- Implants must NOT BE processed with NaOH but can be processed without damage with a sodium hypochlorite solution (6 chlorometric degrees) for 60 min at 20 °C.
- In all cases, do not use a wire brush or an abrasive, and handle products with gloves throughout the different processes and uses, during which they must be arranged on appropriate trays for cleaning and decontamination steps.

b) Sterilisation

- Before use, this product must be sterilised by steam autoclaving in appropriate containers provided by KISCO International, in compliance with ISO standard 17665-1.
- The validated process specified by KISCO International is a cycle at 134 °C – 18 min in a pre-emptied autoclave, followed by 20 min drying. Consult document entitled "Recommendations for maintenance, cleaning and sterilisation of medical devices"*.
- In case of a method different from the aforementioned, it is up to the health institution to validate compatibility of products with its sterilisation process.
- The aforementioned parameters are valid only for devices in the product range sterilised in the corresponding box. Any other configuration used jeopardised validation by the manufacturer.
- Re-sterilisation with steam does not damage implants and is not limited over time.
- Look for any sign of premature wear of implants after sterilisation. If such is the case, DO NOT use them and inform KISCO International (see § 13).

9. INSTRUCTIONS FOR USE

Instructions for placement of implants are detailed in the surgical technique*.

In case of doubt concerning use, cleaning, decontamination, sterilisation, discarding or discarding of an implant, do not hesitate to contact the KISCO International customer service department or its certified distributor.

a) Before the operation

- Read the surgical technique carefully.
- Prepare all bone implants and instruments necessary for the procedure and check their integrity.
- Only KISCO instruments for implant placement, studied and provided by KISCO International should be used in association with the implant.
- Handle implants with care to prevent deep scratches (risk of start of a rupture).
- Assess the height and number of implants to install based on a preoperative radiograph.
- After taking the measurement, plan to have implants in different sizes considered in order to have a sufficient choice during the surgical procedure.
- Always plan to have an extra implant in each required size in order to replace it in case of accidental contamination during the procedure.
- Before a first implantation, the surgeon and his surgical team should practice handling the instruments to become familiar with the equipment.

b) During the operation

- The procedure should be performed by a surgeon who has received the necessary training in spinal surgery.
- Comply with the different phases described in the surgical technique*.
- The implantation must be performed solely with the instruments provided for this purpose and according to the indications of the surgical technique*.
- Sudden spreading apart can cause oedema.
- Perioperative bleeding from an epidural vein must necessarily be managed by gentle application of haemostatic swabs or bipolar coagulation under microscopic control.
- Use an imaging intensifier to check the position of the implants (2 implants per level).
- The cage must never be unscrewed, except in case of permanent removal. **Unscrewing/re-screwing is prohibited** because it can alter the mechanical properties of the implant.

c) After the operation

- Radiological examinations must be performed regularly to check on postoperative progress and thus prevent possible complications.
- Implants are not planned to resist anatomical mechanical stresses beyond one year without a concomitant consolidation of the bone graft.

10. ADVERSE EFFECTS

- Displacement or expulsion of the implant before bone fusion requiring another surgical procedure
- Infection at the implantation site
- Pseudarthrosis
- Neurological damage (a breach of the dura mater, lesion of a spinal root)

11. ELIMINATION OF PRODUCTS

To discard products which have been implanted, these must above all be disinfected and decontaminated. This information which is mentioned on the accompanying liaison form is sent with products returned to KISCO International.

For the disposal of a product following an error in storage, use or at the end of the shelf life of the product, implants must follow the pathway for the disposal of hospital waste products in compliance with procedures in force in the institution.

12. MEANING OF SYMBOLS USED

	Do not use is package is damaged

13. GUARANTEE

In case of a defect, contact the KISCO International customer service department and return the defective implant, cleaned, decontaminated and together with the liaison form.

* Documentation is available on request on the www.kisco.fr website, under the heading "KISCO PRODUCT RANGE".

KISCO International
Parc Technologique – 2, Place Berthe Morisot
69800 SAINT-PRIEST – France
Tel: +33 (0)4.78.90.85.59
Fax: +33 (0)4.78.90.85.18
Website: www.kisco.fr