Manufactured by

L-Varlock Lumbar Posterior Cage
INSTRUCTIONS FOR USE

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Caution: Under federal law, this device may only be sold by or on the order of a physician.

1. **INTRODUCTION** The L-Varlock cage is used for posterior vertebral interbody fusion with restoration of both disc height and lumbar lordosis.

   Advantages of the system

   - Wide range of implants:
     - different heights for accurate enlargement of the foramina
     - different widths and lengths to achieve excellent stability at the instrumented level(s), while preserving the patient's anatomy.
   - Intraoperative adjustment of cage expansion for accurate restoration of the lumbar lordosis and secure wedging of the cage in the intervertebral space.
   - Large graft compartment for good graft incorporation.
   - Reduced operative time thanks to a simple set of dedicated instruments, which assures a straightforward and accurate technique.

2. **DESCRIPTION OF THE EQUIPMENT** The L-Varlock interbody cages are expandable devices. Tightening of the adjusting screw provides expansion of the front of the cages (posterior approach). When driven posteriorly, the roller opens the jaws of the cage, thus restoring the desired amount of lordosis. The L-Varlock cages are available in two versions: standard and narrow. Their toothed outer walls provide good anchorage in the endplates. The posterior end of the cage features a dovetail for connection of the cage holder/impactor.

   Size: The standard and narrow designs have specific lengths and widths:

   - standard design: Width 13mm, Length 27mm
   - narrow design: Width 10mm, Length 22mm

   Each version is offered in different heights (a complete list of implants and instruments is available upon request).

   Material: All L-Varlock cages are manufactured from titanium alloy (Ti-6AL-4V-Eli) according to medical norm ISO 5832-3.

3. **INDICATIONS**: The L-Varlock Lumbar Cage is 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. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). L-Varlock Lumbar implants are to be used with autogenous bone graft and implanted via an open posterior approach. L-Varlock Lumbar implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

4. **CONTRA-INDICATIONS**
   - Allergies or other reactions to titanium alloy, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
   - Active infection.
   - Patient's physiological or psychological state.
   - Patient's bone quality (e.g. significant osteoporosis) which would increase the surgical risk as regards to the mechanical stability of the implant.
   - Tumors.
   - Fractures.

5. **CONDITIONS FOR STORAGE**: Implants and instruments available should be stored away from sunlight, dampness and at room temperature.

6. **INFORMATION/WARNINGS**
   - Implants are for single use only and are delivered NON-STERILE. They are intended to be cleaned and sterilized according to the instructions in paragraphs 7 and 8.
   - Any implant which has been implanted cannot be reused. Depending on duration of implantation, the upper layer of the material undergoes alteration and its mechanical properties no longer will be the same. In case of an error in use, the implant is not designed for mechanical cleaning without risk of deterioration. In such a case, residual contamination of the implant cavity will not make it possible to ensure device safety.
   - Compliance with preoperative and perioperative procedures, including knowledge of surgical techniques, adequate reduction, as well as proper selection and positioning of implants are important factors in successful use of the system by the surgeon. In addition, appropriate selection of patients and cooperation of the latter greatly affect results. It has been demonstrated that patients who are smokers will tend to have less optimal consolidation in spinal fusion surgery.

7. **CLEANING BEFORE STERILIZATION/RESTERILIZATION**
   - 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 sterilization.
   - 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.

   MANUAL PRE-CLEANING:

   - Fully immerse the medical devices in a Neodisher® Mediclean 0.5% solution at room temperature (20°C +/- 5°C) and allow to soak for 10 minutes.
   - Remove visible soil using a soft-bristled brush (non-metallic), brush for 2 minutes. Clean each cavity with care.
   - Remove devices from the Neodisher® Mediclean 0.5% enzymatic solution. Rinse devices using tap water, at room temperature (20° +/- 5°C) for a minimum of 1 minute. Thoroughly rinse each lumen, roughness, hard-to reach areas, cavities...
   - Load the devices in open position in the load-rack of the washer.
   - Launch the cycle of the washer.

   AUTOMATIC PRE-CLEANING: Validation has been performed with the "VARIO-TD" program and the "Neodisher® Mediclean" cleaning product:

   - Prewashing: <45°C, 2 min
   - Washing: 55°C, 5 min
   - Neutralization: tap water temperature, 2 min
   - Rinsing: with cold tap water, 2 min

- Heat disinfection: demineralized water, 90°C, 5 min
- Drying: 22 min
- 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.

8. STERILIZATION

- The implants are for single use and are delivered in a NON-sterile state.
- Before use, this product must be sterilized by steam autoclaving in appropriate containers in compliance with ISO 17665-1, ISO 17664, AAMI TIR 12 and ANSI/AAMI ST79 standards.
- 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.
- In case of a method different from the aforementioned, it is up to the health institution to validate compatibility of products with its sterilization process.
- The aforementioned parameters are valid only for devices in the product range sterilized in the corresponding box. Any other configuration used jeopardizes the validation by the manufacturer.
- Re-sterilization with steam does not damage implants and is not limited over time.
- Look for any sign of premature wear of implants after sterilization. If such is the case, DO NOT use them and inform KISCO International.

9. PRECATIONS TO OBSERVE: The L-Varlock Lumbar Posterior cage has 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 L-Varlock Lumbar Posterior cage in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Preoperative

1. Carefully read the operating technique manual.
2. Carefully read the instrument and implant verification documents (IVD, AVD).
3. Prepare all the implants and instruments required for the operation. Using the implant and instrument verification documents, check that there is nothing missing and carry out the functional and hygiene inspections.
4. Handle the implants with care to avoid any deep scratches (risk of subsequent fracture).
5. Assess the size and number of implants required from the pre-operative x-ray.
6. After carrying out the measurements, ensure that implants of the various sizes selected are available so that there is sufficient choice.
7. Make sure that the anteroposterior iliac bone graft donor site is conveniently draped free.
8. Always allow one extra implant in each of the sizes requested so that an implant can be replaced if accidentally contaminated during the operation.
9. Only the instruments designed and supplied by Kisco International should be used with the implant.
10. Before carrying out a first implant, the surgeon and assistants in the operating theater should handle the instruments to familiarize themselves with the equipment.
11. Check for proper function and fit of the intended cage holder, after it has been sterilized.

During the operation

1. The operation must be carried out by a practitioner with the necessary training in spinal surgery.
2. Comply with the various phases described in the surgical technique.
3. Perioperative bleeding from an epidural vein must necessarily be managed by gentle application of haemostatic swabs or bipolar coagulation under microscopic control
4. Once the cages are seated, the nerve roots must be checked visually.
5. Posterolateral bone grafting is performed to ensure complete bony fusion.
6. The case should be placed at the most unstable level.
7. The nerve root retractor should be used whenever the surgeon works proximal to a nerve root.
8. The use of two interbody cages is highly recommended for proper stabilization of the spine.
9. L-Varlock cages must be associated to a posterior instrumentation.
10. Release distraction of the disc space before expanding the cage.
11. To expand a cage, tighten the posterior adjusting screw. Expand the two cages slowly and alternately. Full expansion may not be necessary.
12. **Caution**: The expansion screws must never be unscrewed, except of course in the case of cage removal.
13. Check the position of the cages using image intensification.
14. The implantation must be performed solely with the instruments provided for this purpose and according to the indications of the surgical technique.
15. Do not tighten the implants too much with the impactor so that you will not be able to un-tighten them.
16. The cage size choice is paramount for the surgery success.
17. The cage expansion aim is not to restore disc height but only to adjust the lordosis angle to anatomy.

After the operation

1. A rehabilitation program with gentle exercises should be stated according to the surgeon's directions.
2. Throughout the healing period, patients are requested to comply with the surgeon's directions and the physical therapist's recommendations.
3. It takes between 3 and 6 months to abolish all pain. The patient can usually resume activities about 5 months after surgery.
4. Periodic X-rays are recommended for close comparison with postoperative conditions, to monitor and evaluate the situation and thus avert potential complications.
5. As the patient is pain free after surgery, he is not inclined to restrain his range of motion, which may compromise bone fusion.

10. UNWANTED SIDE EFFECTS

- Fracture of the cage, adjusting screw or roller.
- Migration or back out of the cage before bony fusion is achieved.
- Pseudoarthrosis.
- Infection at the implantation site.
- Allergies and other reactions to metal, although infrequent, particularly with titanium alloy, should be considered and tested for, and ruled out preoperatively.

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