ODALYS
Posterior thoraco-lumbar osteosynthesis system
INSTRUCTIONS FOR USE

NON STERILE

CE 0499
2007

1. PURPOSE OF MEDICAL DEVICE

The ODALYS system makes it possible to perform thoraco-lumbar osteosynthesis by posterior approach.

2. INDICATIONS

- Degenerative spondylolisthesis
- Spinal stenosis
- Vertebral instability (degenerative)
- Fractures
- Degenerative disc
- Bridging of a tumour
- Spinal deformity (congenital, idiopathic, or neuromuscular)

3. CONTRA-INDICATIONS

- The bony condition of a patient (ex.: massive osteoporosis) making the procedure risky in terms of mechanical securing of the implant
- Congenital spinal stenosis.
- Comminuted fractures involving several vertebrae
- Tumours involving several successive vertebrae
- Allergies, intolerance and/or hypersensitivity to the component material of the implant: titanium (and alloys)
- Primary or secondary infection
- Local inflammation
- Fever, leucocytosis
- Obesity
- Pregnancy
- Mental illness or patient not likely to follow the surgeon's recommendations
- Congenital abnormal anatomy
- Rapidly progressive joint disease, severe osteoporosis
- Inappropriate anatomy
- Patient not having a sufficient quantity of soft tissue to cover the implanted site

4. DESCRIPTION OF MATERIALS PROVIDED

Implants are for single use only and are delivered non-sterile, initially in a metal box with trial implants and instruments. Subsequently, each implant is provided non-sterile in a unit packaging, comprised of:

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

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.

TECHNICAL CHARACTERISTICS:

- Materials: all implants are made of titanium alloy Ti-6Al-4V ELI in accordance to medical standard ISO 5832-3 and ASTM F136.
- A multi-implant system comprised of:
  - 4 families of pedicular screws: monoaxial, polyaxial, polyaxial for spondylolisthesis, monoaxial for spondylolisthesis
  - straight and curved rods
  - locking caps
  - transverse connection devices
  - 5 families of hooks: pedicular, laminar, extended, angled and offset
- Several variations according to the following characteristics:
  - screws: length/diameter/width of the "U"
  - rods: length/diameter
  - transverse connection devices: length/diameter of hook
  - hooks: size of blade/width of "U"/direction

- Pedicular screws have morphologically adapted bone threading (spongy/cortical bone). They are fitted with a head which receives the rod and a locking cap. The width of the "U" corresponds to the rod diameter.
- Spondylolisthesis screws have a longer threaded head and scored to ensure reduction of the deformity.
- The "U" shaped head of the monoaxial screws is fixed in relation to the axis of threading, while that of polyaxial screws is mobile around the axis of threading, enabling adaptation of the assembly to its surroundings (direction of screws, anatomy). Their angle of rotation is 360° (40° incline).
- Pedicular hooks have a groove at the end of the blade enabling them to be placed as a stop against the pedicle.
- Laminar or extended hooks can be used in combination with pedicular hooks to form a pediculo-laminar claw..
- Angled hooks have a 30° inclined blade compared to the sagittal plane.
- Transverse or offset hooks have a 17 mm shifted head in relation to the rod.
- Straight and curved rods, to be assembled on pedicular screws or hooks, can be modified with the tapering instrument to adapt to the setting as best as possible.
- Locking caps make it possible to assemble the rods on the screws or hooks and to lock the assembly in place after adjustment.
- Transverse connection devices confer rigidity on the assembly.

5. MATERIAL NECESSARY FOR THE PLACEMENT OF THE IMPLANT

The kit containing the ODALYS 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 re-use 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.

⚠ b) Warning for 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 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:
  - Pre-washing: < 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 such 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 ISO 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*.
- KISCO International ensures performance of the aforementioned implants if they are used together and not in combination with implants from other manufacturers.
- KISCO International declines all responsibility in case of implantation of a device previously altered by the user (dimensions, surface condition, etc.).
- ⚠ It is prohibited to perform un-tapering of rods.
- Excessive spreading 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.
- Final tightening of blocking screws must be performed with the adequate dynamometric module provided to ensure rigidity of the assembly.

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

The following adverse effects have been observed:

- Displacement or expulsion of the implant before bone fusion requiring another surgical procedure
- Infection at implantation site
- Pseudarthrosis
- Neurological damage (a breach of the dura mater, lesion of a spinal root)
- Vertebral fracture
- Disassembly, deformity and/or rupture of one or more components of the system
- Fragility of the system during growth in a young patient

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 removal of hospital waste products in compliance with procedures in force in the institution.

12. MEANING OF SYMBOLS USED

	Do not use if 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