# PINA® Medizintechnik Vertriebs AG

## Instructions for Use
## of the PINA® CERVICUS*Titan* Cervical Cage System, non-sterile

### 1. General conditions of use
The instructions for use and the information on the product-specific surgical technique must be read carefully and the manufacturer's instructions followed. Upon receipt and before use, check the identity, completeness and integrity of the product. It is important that all requirements and specific information described in the Instructions for Use are taken into account. The implants must be inserted by a qualified surgeon with the necessary training in spinal surgery. The decision on their use must be taken in consideration of the medical and surgical indications, the possible risks and limitations of this type of surgery, the indications, the precautions and side-effects outlined in these instructions, the type of materials and the mechanical properties of the implants used considering the surgical techniques recommended by PINA® Medizintechnik Vertriebs AG. The operative procedure for the CERVICUS*Titan* Cervical Cage System from PINA® Medizintechnik Vertriebs AG is described in the surgical technique. A precise, pre-operative planning of the positioning of the implant based on X-rays, computer tomographies, etc. is absolutely essential. The size of the implants cannot usually be planned before the operation, but is determined during the operation itself. All of the instruments are designed such that they help the surgeon determine the appropriate size of the implant.

### 2. Intended use
The PINA® CERVICUS*Titan* Cervical Cage System is indicated for the anterior fusion of cervical vertebral bodies in patients with a mature skeleton suffering from cervical diseases on level C2 to C7.

### 3. Description
The invertebral CERVICUS*Titan* Cervical Cage System from PINA® are implants intended for implantation between the end plates of the individual vertebrae on level C2 to C7. The implants can be inserted via a lateral anterior approach to the cervical spine. Their shape is adapted to the morphology of the intervertebral spaces being treated and the prescribed surgical techniques. The CERVICUS*Titan* Cage System consists of cages that differ in length, width and height. The implant is delivered non-sterile. It is an implant for single use only and should not be reused under any circumstances.

### 4. Material
The PINA® CERVICUS*Titan* Cervical Cage System are made of a biocompatible titanium alloy (Ti6Al4V) according to ISO 5832-3.

### 5. Indications
The products of the PINA® CERVICUS*Titan* Cervical Cage System are used in adults with the following complaints:
- degenerative discogenic diseases and instabilities
- degenerative spondylolisthesis
- spondylolisthesis with constriction
- revision surgery
- unsuccessful conservative treatment for more than 6 weeks
- all pathologies requiring ventral support of the cervical spine, respecting the contraindications

### 6. Contraindications
The following contraindications may be relative or absolute and must be considered by the physician in his decision making. Surgeons must discuss the appropriate contraindications with the patient.

#### 6.1 Absolute contraindications
- acute or chronic infections of the osseous structure of the vertebrae
- bone tumours in the area of the implant anchor
- expected excessive strain on the implant
- fractures in the area of the implant anchor
- allergies to the material used (Ti6Al4V)
- not intended for use in the area of the lumbar spine

#### 6.2 Relative contraindications
- osteoporosis or similar bone loss
- bone tumours in the area surrounding the implant
- poor general state of health of the patient

- drug abuse, alcoholism
- psychosocial problems, lack of cooperation by the patient
- pregnancy
- infections and inflammatory symptoms

**7. Risks**

Potential risks in connection with the operative procedure are:

- neural complications caused by over-distraction or traumatisation of the nerve roots or the dura mater
- loss of intervertebral disc height, caused by the removal of healthy osseous material
- Injuries to the oesophagus, vocal cord nerves, cervical vessels caused during access
- common risk of surgical interventions, such as bleeding or haematoma
- death

**8. Possible side-effects**

- delayed consolidation of the fusion, no visible fusion and pseudoarthrosis
- pain following surgery
- migration of the implant
- breakage of the implant
- superficial or deeper infection and inflammatory symptoms
- allergic reactions to the implant's material
- the implant may sink into the vertebra
- neuralgic symptoms
- decreasing bone density due to an altered distribution of the mechanical load

The appearance of one or several side-effects may necessitate renewed surgery.

**9. Important notices**

The patient must be informed about the advantages and disadvantages of the procedure. The patient's weight and activity should be taken into account when selecting an appropriate implant. Smoking tobacco has a harmful effect on the bone fusion and is associated with the risk of pseudoarthrosis. Patients who are smokers should be informed of this. The use of the implant assumes a detailed knowledge of spinal stabilisation and the biomechanical circumstances of the spine. The implants may only be used with the special instruments of the PINA® CERVICUS*Titan* Cervical Cage System. The surgeon must plan the operation with respect to the choice of implant and its position before beginning the operation. It also has to be ensured that all necessary implants are available and that the implantation instruments are complete and in perfect working order. Never use an implant that is damaged, has been explanted or one with which a fault has occurred during use, or with which the patient has come into contact, even after cleaning. The implant has to be disposed correctly. The re-use of a device that is intended for single use is barred by both the warranty of structural integrity and the achievement of the performance over the specified period and could lead to its premature failure. This kind of re-use could also lead to a contamination of the patient.

**10. Disposal**

The removed implants must not be reused and must be disposed. The implants consist exclusively of biocompatible materials and are absolutely innert with regard to disposal. The implants can therefore be disposed of with the standard surgical waste in the clinic.

**11. Packaging**

The implants are delivered in non-sterile packaging: the packaging must be undamaged on receipt. All information required by law for this type of implant can be found on the packaging label.

**12. Recommended method for cleaning and sterilising of non-sterile delivered medical instruments and implants**

**Detailed information can be found in the re-processing instructions of PINA Medizintechnik Vertriebs AG**

**12.1 Cleaning before sterilisation**

Wash in the machine with a broad-spectrum bactericide and fungicide. We recommend using aqueous solutions with a pH value over 4. An oxidation test should be carried out before using any cleansing agent.

**12.2 Inadmissible cleansing agent**
Strong mineral acids (sulphuric acid, nitric acid, hydrochloric acid, etc.) or strong Lewis acids such as zinc chlorite or sodium hypochlorite, caustic soda or strong concentrations of hypochlorite or permanganate ions. Avoid any longer dwell times in aggressive solutions such as ethylene dichloride, phenol solutions, aniline solutions or the like at high temperatures.

**12.3 Precautions**
Exclude any abrasive products or instruments (sponges, metal brushes etc.). We recommend that you check the condition and proper functioning of the instruments after every cleaning and sterilisation process.

**12.4 Drying**
We recommend leaving the instruments to dry fully before sterilisation so as to guarantee the elimination of all mineral deposits.

**12.5 Sterilisation**
Use the storage dishes for sterilisation and sterile provisioning. Pay attention to the following if sterilising with steam: sterilisation must be carried out in accordance with a validated steam sterilisation procedure (e.g. in a steriliser pursuant to EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993 and validated pursuant to EN 554/ISO 13683). If using the fractionated vacuum method, sterilisation must be carried out by the 134 °C/2 bar program with a minimum hold time of 10 minutes.

**13. Complaints**
Any expert (customer or user) who is not satisfied with the work/services and/or the quality, identification, resilience, reliability, safety, efficacy and/or performance of PINA® Medizintechnik Vertriebs AG products must report this in writing to the representative or authorised dealer of PINA® Medizintechnik Vertriebs AG. The authorised dealer will send PINA® Medizintechnik Vertriebs AG this complaint as quickly as possible in a problem report. If a malfunction, damage to the device or any kind of error in the instructions for use has or could have caused the death or serious impairment to the health of a patient or user, this must be reported immediately by phone. The report of such an incident must contain as much information as possible (name of the product, article number, serial number, LOT number, etc.), the type of complaint or an exact description of the incident, the consequences and any technical elements that could facilitate the future expertise (implant components, X-rays, etc.).

**Further information**
Please contact the manufacturer PINA® Medizintechnik Vertriebs AG or the authorized distributor if you require further or up-to-date information or documentation on this product. This instruction for use and the corresponding surgical techniques can also be downloaded from the PINA® website: www.pina-med.ch

**Explanation of symbols**

The following symbols may appear on labels. The meanings of the symbols are defined by ISO 15223-1.

| Symbol used | Explanation |
|---|---|
|  | (Manufacturer)<br>PINA® Medizintechnik Vertriebs AG<br>Lagerhausstrasse 18, CH - 8400 Winterthur |
|  | LOT code |
|  | Article number |
|  | Non-sterile |
|  | Do not use the product if the packaging is damaged |
|  | Pay attention to the instructions for use |
|  | Caution, pay attention to the instructions for use |
|  | Do not reuse |
|  | Store in a dry place |
|  | Keep away from sunlight |
| CE | Conformity mark for class I medical products (non-sterile and without measuring function) |
| CE 0297 | Conformity mark for class IIa and higher medical products. Number of the recognised testing laboratory |

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Should you require further information, or if you wish to report a complaint, please contact:

CE 
**0297**

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