PINA® Medizintechnik Vertriebs AG

Instructions for Use
of the cervical PINA® ECHINUS*Invadur Ti-coated* Cage System, 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 considered. The surgical procedure for the cervical ECHINUS*Invadur Ti-coated* cage system is described in the surgical technique. Accurate pre-operative planning of the positioning of the implant based on X-rays, computer tomography scans, etc. is absolutely necessary. The size of the implants cannot normally be planned pre-operatively, but is determined intraoperatively. All instruments are designed to help the surgeon determine the appropriate implant size.

2. Intended Use
The PINA® ECHINUS*Invadur Ti-coated* cage system is indicated for the anterior fusion of cervical vertebral bodiesin patients with a mature skeleton suffering from cervical diseases on level C2 to C7.

3. Description
The intervertebral ECHINUS*Invadur Ti-coated* Cages from PINA® Medizintechnik Vertriebs AG are implants intended for implantation between the end plates of the individual vertebral bodies on the level from 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 treated intervertebral spaces and the prescribed surgical techniques. The cages are available in various designs (tapered and arched) and sizes. The implant is supplied as gamma sterilized single-use implant and must not be resterilized under any circumstances. It is a single-use implant and must not be reused under any circumstances.

4. Material
The PINA® ECHINUS*Invadur Ti-coated* cages are made of PEKK, a polymer from the PEAK group that has been specially developed for implants and that is biocompatible, X-ray transparent, CT- and MRT-compatible. The marking pins are made of titanium alloy (Ti6Al4V) according ISO 5832-3). The coating consists of titanium VPS according to ASTM F1580-01 and ISO 5832-2.

5. Indications
The products of the PINA® ECHINUS*Invadur Ti-coated* cage system are used in adults with the following complaints:
- degenerative discogenic diseases and instabilities
- degenerative spondylolisthesis
- post-traumatic instabilities
- 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 (PEKK, titanium, titanium alloy (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. Intended Patient Group
The product should be used considering the intended use, indications, contraindications and the patient's anatomy and state of health.

8. Intended User
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.

9. 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

10. 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.

11. Important Notices
The patient must be informed about the advantages and disadvantages of the procedure. The patient's weight and activity should be considered 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 cervical PINA® ECHINUS*Invadur Ti-coated* cage system. Prior to surgery, the surgeon must plan the operation with respect to the choice of implant and their positioning. It must also be ensured that all necessary implants are available and that the implantation instruments are complete and functional. Never use damaged implant, an explanted implant or an implant where an error has occurred during use or has come into contact with the patient, even after cleaning. The implant must be disposed correctly. Re-use of single-use device does not guarantee its structural integrity or that it will perform as prescribed over time and could result in premature failure. Such reuse could also lead to contamination of the patient.

12. 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.

13. Packaging
The implants are delivered sterile packed and ready for use. The packaging must be undamaged on receipt. All information required by law for this type of implant can be found on the packaging label.

14. Recommendation for Implants delivered in a sterile Condition
It is recommended to check the expiry date for sterility before using the implant. PINA® Medizintechnik Vertriebs AG is not liable for the use of products beyond the expiry date. If the packaging is damaged, opened or the expiry date on the product label has been exceeded, the implant must no longer be used. Sterility is only guaranteed if the packaging is not damaged in any way. The implant must not be re-sterilised under any circumstances if damaged or after the packaging has been opened.

15. Recommended method for cleaning and sterilizing of non-sterile delivered reusable surgical Instruments

Detailed information can be found in the (re-) processing instructions of PINA® Medizintechnik Vertriebs AG.

15.1 Cleaning before sterilization
Wash in the machine with a broad-spectrum bactericide and fungicide. We recommend using aqueous solutions with a pH value above 4.0. An oxidation test should be carried out before using any cleansing agent.

15.2 Inadmissible Cleansing Agent
Strong mineral acids (sulfuric acid, nitric acid, hydrochloric acid, etc.) or strong Lewis acids such as zinc chloride or sodium hypochlorite, caustic soda or strong concentrations of hypochlorite or permanganate ions. Avoid prolonged residence at high temperatures and in aggressive solvents such as ethylene dichloride, phenol solutions, aniline solutions or similar.

15.3 Precautions
Exclude any abrasive products or instruments (sponges, metal brushes etc.). It is recommended to check the condition and proper functioning of the instruments after every cleaning and sterilisation process.

15.4 Drying
It is recommended to allow the instruments to dry completely before the sterilization process to ensure elimination of any mineral substance deposits.

15.5 Sterilization
Use the storage dishes for sterilization and sterile provisioning. Pay attention to the following if sterilizing with steam: sterilization must be carried out in accordance with a validated steam sterilization 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.

16. 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 or by e-mail. 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 authorised distributor if you require further or up-to-date information or documentation on this product. The present instruction for use can be downloaded from the PINA® website: www.pina-med.ch

With full functionality of the EUDAMED website, the Summary of Safety and Clinical Performance (SSCP) can be accessed at https://ec.europa.eu/tools/eudamed

For more information or to report a complaint or incident, please contact:

CE 

0297

PINA® Medizintechnik Vertriebs AG
Neuwiesenstrasse 15
8400 Winterthur
Switzerland
Tel.: +41 44 586 52 62
www.pina-med.ch
info@pina-med.ch

EC REP 

Bricon GmbH
Eisenbahnstrasse 100
78573 Wurmlingen
Germany

Explanation of Symbols

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

Symbol used	Explanation	Symbol used	Explanation
	(Manufacturer) PINA® Medizintechnik Vertriebs AG Neuwiesenstrasse 15, CH – 8400 Winterthur		Patient Identification
 YYYY-MM-DD	Date of manufacture		Website with patient information
	(Authorized representative in the European Union) Bricon GmbH, Eisenbahnstrasse 100, D- 78573 Wurmlingen		Ambulance or physician
	(Importer) Bricon GmbH, Eisenbahnstrasse 100, D- 78573 Wurmlingen		Date
	Batch code		Do not use if the packaging is damaged, follow the instructions for use
	Article number		Do not re-sterilize
	Medical device		Do not reuse
	Unique Device Identification		Protect from sunlight
	Radiation-sterilized		Store dry
	Simple-sterile-barrier-system		Follow the instructions for use
	Double-sterile-barrier-system		Attention
 2009-06-28	Usable until	 0297	Conformity marking with Notified Body DQS Medizinprodukte GmbH, August-Schanz-Straße 21, D- 60433 Frankfurt am Main
Lit. No.: IFU_ECHINUS Invadur sterile_EP_EN_Rev07			