medicon®
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

English

CE 0123 Rx only STERILE R MD



instructions for use

**Carefully read the operating instructions and the "Surgical technique and instruments" brochure prior to clinical application and keep them safe and at hand. The instructions and notes contained therein must be followed. MEDICON eG will assume no liability for the application, unless appropriate introduction has been provided**.

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## 1. GENERAL NOTES

The MEDICON "MediCage®-TLIF sterile" is made of titanium. The material is biocompatible, corrosion-resistant and non-toxic in a biological environment. The surface is chemically passive; the material is antimagnetic.

**The implants are not reusable and are supplied sterile. Please observe the following notes. These will ensure flawless and reliable functioning of the product.**

The reusable surgical instruments are made of stainless materials. The material is corrosion-resistant and has excellent properties in a biological environment.

## 2. INTENDED USE AND INDICATION

The MEDICON "MediCage®-TLIF sterile" may be implanted only in hospitals and clinical practices by surgeons with sufficient experience in spinal operations (neurosurgery, orthopaedics, trauma surgery, etc.) who have received an appropriate introduction to the system.
The "MediCage®-TLIF sterile" may be used only by surgeons with experience in surgery of the lumbar spine. The implant serves to immobilise and stabilise one or several segments of the lumbar spine in patients with completed skeletal growth. The system can be used for the treatment of degenerative intervertebral disc disorders of the lumbar spine that require interbody fusion, for example disc-related acute or chronic instabilities, stenoses or deformities that have been confirmed by imaging examinations, or in combination with additional fixation, for example with the "MediRod® pedicle screw-rod system", where prior reinforcements have failed (pseudarthrosis).
The MEDICON implants are single-use products and may be used only in combination with the specified MEDICON application instruments.

## 3. CONTRAINDICATIONS

Conditions that can demonstrably be safely and foreseeably treated without internal fixation aids are relative contraindications. An implant is contraindicated in case of active systemic infection or local infection at the planned implantation site. Severe osteoporosis should be mentioned here as a further example. All situations and illnesses that might reduce the possibility of bone growth, such as neoplastic disease, functional disorders of the kidneys or liver, or osteopenia, are deemed relative contraindications.

Sensitivity to foreign objects, allergies and certain degenerative or mental illnesses are considered further relative contraindications. This applies in particular to patients who subject the implant to increased pressure during bone healing, for example due to their occupation, lifestyle, severe obesity, degenerative illnesses, mental limitations or illnesses such as mental disorders, alcoholism or drug abuse. This increases the risk of implant subsidence with secondary constriction of root or spinal canal, misalignment or pseudarthrosis formation.

## 4. POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

Possible undesired effects and complications associated with the "MediCage®-TLIF sterile" include, without being limited to:

- Failure of the implant due to loosening in the bone
- Failure of the implant due to insufficient bone fusion or insufficient reinforcement of the area operated on and thus absence of mechanically stable conditions
- In the event of a lack of cooperation on the part of the patient, or where cooperation cannot possibly be obtained, pseudarthrosis formation and/or implant failure and dislocation may occur
- Loose implants can lead to secondary irritations or injury to adjacent anatomical structures such as spinal cord, nerve roots, blood vessels or internal organs
- Incorrect implantation of the implant may lead to spinal fractures, damage and injury to the spinal cord or adjacent anatomical structures, nerve root damage, or even to paraplegia.
- Incorrect size selection of the "MediCage®-TLIF sterile" can lead to secondary disorders
- Material hypersensitivity of the patient in the form of allergic reactions
- Discomfort, pain, abnormal sensations due to the implant
- Breaking, bending, migration, loosening of the implant and/or further surgical intervention to remove the system
- Early or late infections
- Neurological damage resulting from the surgical trauma or the presence of the implant. Neurological symptoms, including bowel and/or bladder dysfunctions, impotence, retro-grade ejaculation and paraesthesia, paraplegia
- Injuries to the dura mater occurring during the operation may require further surgical intervention to restore the dura, and may lead to a continued leakage of cerebrospinal fluid or a fistula, and under certain circumstances may even lead to meningitis
- Vascular damage, above all in the region of the operative access, as a result of surgical trauma. Vascular damage may lead to life-threatening or fatal haemorrhages. Incorrectly positioned implants in the vicinity of large blood vessels may erode these vessels and lead to life-threatening haemorrhages – even in the late postoperative period
- Degenerative changes or instability in segments that are ad-jacent to a stiffened spine

When the "MediCage®-TLIF sterile" remains in the body after full recovery, the following complications may occur, either individually or collectively:

- Corrosion with localised tissue reaction or pain
- Changes in the position of the implant with consequent injuries
- Risk of additional injuries due to postoperative trauma
- Bending, loosening and/or fracture, making follow-up operations more difficult
- Pain, discomfort or non-physiological sensations due to the presence of the product
- Potentially increased risk of infection
- Bone loss caused by stress shielding

In the selection of patients, the following factors should be observed that promote possible adverse events and complications:

**Patient weight:**

- Excess weight or obesity of a patient can increase the load on the implant in such a way that failure becomes likely.

**Occupation or activity of the patient:**

- Heavy lifting, muscle strain, body rotation, repeated bending, stooping, running or manual labour should be avoided in private or occupational activities until to the bones have healed completely. Even after complete healing, the patient may not be able to successfully perform the activities listed above any longer.

**Senility, mental illness, alcoholism or drug abuse:**

- Insufficient ability to cooperate in the context of these circumstances may contribute to the patient ignoring certain restrictions or precautions that the implant calls for. This can lead to failure of the implant or other complications.

**Sensitivity to foreign bodies:**

- Preoperative testing may not entirely exclude hypersensitivity or allergy. Such complications may occur even if the implant has already been in the body for some time.

**Smoking:**

- In smokers, a higher rate of pseudarthroses was found after surgical procedures where bone implants were used.
- Smoking-induced progressive degeneration of adjacent segments can lead to later clinical failure (intermittent pain), even if initially successful reinforcement of the bone has occurred and clinical improvement has been demonstrated.

**In addition to the undesirable effects and complications already mentioned, the surgical procedure can lead to other problems such as nerve damage, infections, pain etc. that are not necessarily attributable to the implant.**

## 5. SINGLE-USE PRODUCT

**Implants are intended and designed for single use on one patient only and may not be reused.**

An explanted implant must never be reused. Even if the implant appears to be intact or fully functional, there may be wear, minor
defects and attrition due to overuse that are not visible to the naked eye. As the impact of the forces and conditions inside the body on the stability, function and material quality of an explanted implant cannot be estimated, reimplantation would entail the risk of premature wear or failure and is therefore unacceptable. The user will be held liable if the operating instructions and the MEDICON brochure "Surgical technique and instruments" are not observed.

## 6. MR SAFETY

**Instruments**
The use of medical devices in the vicinity of an MRI poses a hazard. Individual medical devices must not be located near the equipment during the application of these procedures.
**Implants**
The implants are not MR-safe and have not been tested for MR safety. Therefore, use in an MRI environment may pose a risk. It is recommended to inform patients and medical staff that the implants are not approved for use in MRI devices.

## 7. APPLICATION AND HANDLING

Implant selection:

The surgeon is responsible for correct patient-specific selection and use of the implants.

The following aspects are critical for correct implant selection:

- Indication
- Patient's body weight
- Patient's physical condition, age and level of activity

Incorrect selection of the implants with regard to the aforementioned selection criteria can result in overloading and associated premature implant failure. Only use of the correct components will result in optimally stable fixation, whereas an incorrect decision may lead to loosening, bending or breakage of the implant and/or bone.
The success of an operation depends, among other things, on how the implants are handled. Damage leads to reduction in product strength and premature fatigue of the implant. Implants and instruments are developed and made to be compatible with each other. Using implants and instruments by other manufacturers in conjunction with the MEDICON products is associated with unforeseeable risks, as such products are not designed to be used together.
For this reason, only the specially designed MEDICON products should be used together in order to prevent risks to patients, users and/or third parties. If no bone fusion sets in, or if it is delayed or inadequate, the possibility that the implant will bend, fail or break cannot be ruled out. Therefore adequate immobilisation of the fracture site must be ensured until the bone has grown together again firmly.
The constant load change the implants are subject to may lead to fatigue breakage. It cannot be ruled out that the implants may break, loosen, bend, corrode, migrate in the tissue or cause pain. The implants temporarily stiffen segments of the spine until vertebral fusion occurs; due to the anatomical limitations and despite modern surgical materials, they do not last for an unlimited period. We can therefore assume liability for the implants only until complete healing.

**Use and handling of the "MediCage®-TLIF sterile":**
All implants must be checked for function, deformation and me-chanical integrity prior to implantation. Damaged implants must be replaced, as they can lead to partial or even total loss of function. Always choose the "MediCage®-TLIF sterile" that best suits the specific situation and indication.
Make sure that the "MediCage®-TLIF sterile" is positioned correctly with the aid of imaging procedures. If subjected to excessive stress or used at an unfavourable angle in an application, the "MediCage®-TLIF sterile" may become overloaded and break. This also applies to instruments.

**Use and handling of instruments:**
The instruments intended for application of the implant are subject to wear and mechanical stresses even when used normally, but especially if used too forcefully. In order to prevent failure or mechanical damage to the instruments during surgery, they must be checked before each use to ensure that they are mechanically intact, that there are no deformations, and that the parts are fully functioning.
Damaged instruments must not be used and are to be replaced. Use only accessories and instruments specifically approved by MEDICON, in order to avoid risks in connection with the compatibility of the products. Detailed information about the handling of instruments and safety information can be found in the MEDICON brochure "Surgical technique and instruments".

**The correct application and handling of the instruments is described in the brochure "Surgical technique and instrument preparation". The instructions and notes in this document must be followed.**

## 8. PRE-OPERATIVE AND POST-OPERATIVE CONDUCT

**Pre-operatively:**
Before using the product, the surgeon should thoroughly discuss the desired operation result with the patient. Particular attention must be paid to post-operative behaviour and potentially required follow-up care.

**Post-operatively:**
Post-operative care and the patient's ability to follow instructions are important aspects for successful healing of the bone. The patient must be instructed to immediately inform the surgeon about any unusual changes at the operation site. The patient must be carefully monitored if there are actually changes in the fixation area. The surgeon must consider possible implications such as implant failure, and discuss required measures for further healing with the patient.
The patient must be aware of the limitations enforced by the implant and be instructed to avoid or limit any physical activities, especially lifting and turning movements, as well as participation in sporting activities.
The patient must be aware that a metal implant is not as strong as normal healthy bone and that excess loading – particularly in case of incomplete bone healing – can lead to loosening, bending, and/or breakage. The patient must also be aware that loss of function of the implant may still occur, even if he or she observes these restrictions. Displaced or damaged implants may migrate and damage nerves or blood vessels.
An active, weakened, or demented patient who cannot properly use disburdening walking aids is at particular danger in the post-operative rehabilitation phase. The decision on whether the implants should remain in the body is the responsibility of the surgeon and should be made after considering the risks and benefits of each approach. After explantation, risks should be minimised with adequate post-operative follow-up care. In active patients, the risk may be increased by implants remaining in the body.
After explantation, the surgeon is responsible for disposal of the im-plants according to the standard. A "LOT" number (batch number) is indicated on the label of the packaging. To ensure 100% traceability, we recommend noting down the "LOT" number in the patient records.

**Disposal: Observe the applicable national laws when disposing of the MEDICON system and accessories.**

## 9. STERILITY

The implants are sterilised using radiation and must be stored in their original packaging until immediately before use. The implants may then be removed
from the original and protective packaging. The expiry date and intactness of the sterile packaging must be checked before use.
Implants must not be used after the expiry date. The implant must be free from packaging residues prior to use. If products are reused, there is a risk of infection of patients and/or users, and impairment of proper functioning. Contamination and/or impaired function of the product can lead to injury, illness or death.
The "MediCage®-TLIF sterile" is a sterile product for single use. Products from damaged or broken sterile packaging may not be used, as sterility cannot be guaranteed. The product may not be resterilised.

**The "MediCage®-TLIF sterile" may not be re-sterilised.**

## 10. LIABILITY

In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version is authoritative. Only the latest revision of the operating instructions applies. Due to constant technical development, the content of these MEDICON operating instructions is updated regularly.

The version date of each edition of the operating instructions is included into the printout. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions. MEDICON eG assumes no liability for defects in case of changes or repairs to the product without prior written consent from MEDICON eG either, nor in case of repairs not carried out by workshops authorised by MEDICON eG or by the MEDICON Repair Service.

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English

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## 11. DESCRIPTION OF SYMBOLS AND ICONS

| | |
|---|---|
|  | Observe the operating instructions |
|  | Caution |
|  | CE label acc. to Directive 93/42/EEC |
|  | Manufacturer |
|  | Date of manufacture |
|  | Do not reuse |
|  | Do not re-sterilise |
|  | Sterilised by irradiation |
|  | MR unsafe |
|  | Humidity limitation |
|  | Protect from sunlight |
| Rx only | Subject to medical prescription (US federal law) |
|  | Production lot number, batch |
|  | Item number |
|  | Use by |
|  | Do not use if packaging is damaged |
|  | Store in a dry place |
|  | Temperature limitation |

Please contact MEDICON eG if you have any further questions regarding the implants or instruments.
If you do not have the MEDICON brochure “Surgical technique and instruments” at hand, MEDICON eG can provide an up-to-date copy upon request.

**PLEASE NOTE: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription!**