



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

TABLE OF CONTENTS

1. General notes
2. Intended Use and Indication
3. Contraindications
4. Possible adverse effects and complications
5. Single-use product
6. CT and MRI notes
7. Application and handling
8. Pre-operative and post-operative behaviour
9. Sterility
10. Liability
11. Description of symbols and icons

1. GENERAL NOTES

The expandable vertebral replacement "MediExpand®-TL sterile" is made of alloyed titanium. The materials are 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.

2. INTENDED USE AND INDICATION

The expandable vertebral replacement "MediExpand®-TL sterile" is used for stable, load-bearing reconstruction of the natural height of the removed lumbar and thoracic vertebrae. For dorsal stabilisation, the vertebral replacement must be inserted using a "pedicle screw system". The vertebral replacement "MediExpand®-TL 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 MEDICON implants are single-use products and may be used only in combination with the specified MEDICON application instruments.

3. CONTRAINDICATIONS

MEDICON's expandable vertebral replacement "MediExpand®-TL sterile" must not be used in cases of:

- Severe osteoporosis
- Highly tumorous, destroyed regions of vertebrae
- Anatomically unsuitable parts of the spine
- Other skeletal sections for which it is not intended
- Patients who are unable to comply with the instructions for postoperative care, for example, due to psychological, mental or neurological problems
- Patients in unstable physical and/or mental condition
- Patients with inadequate or low-quality bone tissue, with perfusion problems or latent infections
- Proven allergy to titanium
- Material hypersensitivity, i.e. reaction of the patient to foreign bodies. Here appropriate tests are mandatory before implantation (even in case of acute infections)

4. POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

Possible undesired effects and complications associated with the expandable vertebral replacement "MediExpand®-TL sterile" include:

- 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
- Loosened implants can lead to secondary irritations or injury to adjacent anatomical structures such as the spinal cord, nerve roots, vertebral arteries or the oesophagus
- Incorrect placement of the expandable vertebral body reinjury to the spinal cord, nerve root damage, or even paraplegia
- Selection of the wrong size of the expandable vertebral replacement 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 dysfunction, impotence, retrograde ejaculation and paraesthesia, paraplegia, quadriplegia
- Injuries to the dura mater occurring during the operation may require further surgical intervention to restore the dura, and may lead to continued leakage of cerebrospinal fluid or a fistula, and under certain circumstances even 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 haemorrhaging in the late postoperative period
- Degenerative changes or instability in segments that are adjacent to a stiffened spine
- When the expandable vertebral replacement "MediExpand®-TL sterile" remains in the body after full recovery, any or all of the following complications may occur:
 - 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 body weight or obesity of a patient can increase the load on the implant in such a way that failure is more 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 no longer be able to successfully perform the activities listed above

Senility, mental illness, alcoholism or drug abuse:

- 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 stiffening 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 cannot be attributed to the implant.

5. SINGLE-USE PRODUCT

MEDICON 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 anticipated, reimplantation would entail the risk of premature wear held liable if the operating instructions and the MEDICON brochure "Surgical technique and instruments" are not observed.

6. MR NOTES

Instruments

The use of medical devices in the vicinity of an MR 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 MR environment may pose a risk. It is recommended to inform patients and medical staff that the implants are not approved for use in MR devices.

7. APPLICATION AND HANDLING



Implant selection:

The surgeon is responsible for correct selection of the implants for each individual patient.

The following aspects are critical for correct implant selection:

- Indication
- Patient weight
- Physical condition and level of activity of the patient

Incorrect implant selection can result in premature loosening, bending or implant breakage and therefore lead to loss of function.

All implants must be checked for function, deformation and mechanical integrity prior to implantation. Damaged implants must be replaced, as they can lead to partial or even total function loss.

Implants and devices are developed and manufactured 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 is delayed or inadequate, the possibility that the implant will bend, fail or break cannot be ruled out. 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, migrate in the tissue and cause pain. This makes a further surgical intervention with replacement of the implant necessary.

The implants temporarily stiffen segments of the spine until vertebral fusion occurs; due to the anatomical limitations and despite modern surgical materials, they cannot last for an unlimited period. This means that we can accept liability for the implants only until bone fusion can be assumed under normal conditions.

Use and handling of the expandable vertebral replacement "MediExpand®-TL sterile":

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.

Always choose the vertebral body replacement that best suits the specific situation and indication. Make sure that the expandable vertebral replacement "MediExpand®-TL 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 expandable vertebral replacement "MediExpand®-TL sterile" may become overloaded and break. The tight and correct connection between the implant and the insertion instrument must be checked and ensured prior to implantation.

The same applies, when locking the implant, to the connection between the screw holder and the locking screw. MEDICON's expandable vertebral replacement "MediExpand®-TL sterile" may loosen, thereby changing its height, if the locking screws are insufficiently tightened. A vertebral body replacement whose height setting has changed, resulting in shifting of the implant, may migrate and damage the nerves or blood vessels.

Use and handling of instruments:

The instruments intended for application of the expandable vertebral replacement "MediExpand®-TL sterile" are subject to wear and mechanical stress 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 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. 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 products, the surgeon must thoroughly discuss the desired operation result with the patient. Particular attention must be given 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 unusual in situ changes. The patient must be carefully monitored if there are actual 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 future limitations resulting from the intervention 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 does not have the functionality of healthy bone in the long term, 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 "MediExpand®-TL sterile" may occur despite correct post-operative conduct. Displaced or damaged implants may migrate and damage nerves or blood vessels.

An active, weakened, or demented patient who cannot properly use relieving walking aids is at particular danger in the post-operative rehabilitation phase. The decision on whether the implants should remain in the body or be removed after complete healing is the responsibility of the surgeon and should be made after considering the risks and benefits of each approach. Further risks after an explantation should be avoided by 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 implants 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 guidelines 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 "MediExpand®-TL 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 re-sterilised.



The expandable vertebral replacement "Medi-Expand®-TL 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.

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.



CE 0123



Rx only

STERILE R

MD

11. SYMBOLS AND DESCRIPTION

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| | Observe the operating instructions |
| | Please note |
| | CE label acc. to Directive 93/42/EEC |
| | Manufacturer |
| | Date of manufacture |
| | Not reusable |
| | Do not re-sterilise |
| | Sterilised by irradiation |
| | MR unsafe |
| | Humidity limitation |
| | Keep away from sunlight |
| Rx only | Subject to medical prescription (US federal law) |
| | Batch code |
| | Item number |
| | Use by |
| | Do not use if packaging is damaged |
| | Store in a dry place |
| | Limit temperature |

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!