INSTRUCTION MANUAL

Valid for:
OSTEOSYNTHESIS – IMPLANTATS
made of ISO 5832-1 Implant Steel
for single Use
Item number group: 7xx-0xx-xxx-xxx

GENERAL

General information

The processing of an implant is not permitted if it has already been in patient contact or has been contaminated. Detailed processing information may be found in the enclosed processing instructions for disposable metal osteosynthesis implants

Material

All osteosynthesis implants consist of stainless steel approved for implantation. The materials comply with the standard ISO 5832-1 for implant steel. The material used is identified by the packing label.

Chemical composition Stainless steel ISO 5832-1	
Element	***Mass fraction* %**
Carbon	max. 0.030
Silicon	max. 0.75
Manganese	max 2.0
Phosphorus	max. 0.025
Sulfur	max. 0.010
Nitrogen	max. 0.10
Chrome	17.0 to 19.0
Molybdenum	2.25 to 3.00
Nickel	13.0 to 15.0
Copper	max. 0.50
Cobalt	< 0.10
Iron	remainder

Identification of the implant & securing traceability

The designation of the products and the labelling allow identification of the product. The LOT numbers indicated on the labels must be transferred to the surgery file.

Delivery packaging & storage information

The delivery packaging of the implants is NOT suitable for sterilisation. This is for transport purposes only. Storage conditions: Original packaging, clean, dry, no direct sunlight. It must be ensured that the implants are not altered or damaged by storage.

Important note to the surgeon

All osteosynthesis implants supplied by Hofer GmbH & Co KG (HOFER) are to be used in trauma surgery and orthopaedics. The implant is used for temporary stabilisation until bony fusion has set in. Like other temporary osteosynthesis implant systems, HOFER implants have a limited functional life. Postoperative care is therefore extremely important to assess the stabilisation of bony components and the condition of the implant components. Even with complete bony consolidation, however, deformation, bending, breakage or loosening of the implant components may still occur. Therefore, the patient should be informed that any bending, fracture or loosening of the implant components may occur even if rehabilitation recommendations are followed.

After a complete bone healing, the implants are no longer required and can be removed. The possibility of a second surgery must be discussed with the patient, as well the risks associated with such a second surgery. Every decision to remove an implant must be made by the surgeon under consideration of the general medical condition of the patient and the potential risk for the patient of undergoing a second surgical procedure.
If an implant should fail, the physician must decide to remove it since the risks associated with the condition of the patient and the presence of a failed implant must be taken into account.

Limited knowledge or experience about the used systems can lead to complications.

PREPARATION OF SINGLE-USE METAL OSTEOSYNTHESIS IMPLANTS

Preparation restrictions

Proper preparation has little effect on these products. Preparation of an implant is not permitted if it has already been in patient contact or has been contaminated. All unused disposable products that have come into contact with blood, bone, tissue or body fluids must not be reprocessed but must be disposed of. Implants with signs of corrosion, scratches, nicks, residues or deposits must be discarded. In case of disregard, the manufacturer excludes any liability.

Cleaning & Disinfecting

The implants are shipped NON-STERILE. For the cleaning and disinfection agents to be used, exactly adhere to the information from the manufacturers concerning concentration, exposure time, and temperature. Pay special attention to the critical areas such as movable parts: As a rule, always clean multi-component implants in a disassembled state and open articulated joints beforehand. After cleaning and disinfection, rinse implants with purified water and then immediately dry sufficiently while avoiding germ accumulation. Never use metal brushes. For reprocessing cannulated products and / or products with cavities, you need cleaning pins, bottle brushes and / or disposable syringes with associated cannulas as an attachment. Only use automated reprocessing procedures. The listed parameters apply only to properly installed, maintained and calibrated processing systems that meet the requirements of ISO 15883 and ISO 17665 standards.

Cleaning & Disinfecting: Automated

To ensure hygienic safety, Hofer Medical Solutions products may only be reprocessed by means of mechanical cleaning and disinfection. The following procedure has been validated by Hofer Medical Solutions:

Phase	Temperature	Duration	Agent
Rinsing	≤ 30 °C	min. 1 min	Cold water
Cleaning	≥ 55 °C	min. 10 min	0.5 % neodisher Mediclean forte
Rinsing	10 °C	min. 1 min	AD* or VE water
Thermal disinfection	≥ 93 °C	5 min	AD* or VE water
Drying	110 °C	20 min	

* AD = Aqua Destillata / demineralised water

Inspection, Maintenance, and Check

Inspection after cleaning	Visually inspect the items to be rinsed, especially critical areas (e.g. blind holes, cannulations, joints, etc.), carefully for visible dirt residues and moisture residues. If necessary, repeat the process immediately. **Important:** Avoid renewed contamination of the cleaned medical device. Sufficient cleanliness is a basic requirement for successful sterilisation!
General information	Visual inspections for residues, damage, deformation or corrosion. Imperfect implants should be replaced immediately. Prevent recontamination during inspections!
Care products	Not required.
Functional efficiency check	Not required.

Packaging

Before sterilisation, all products must be placed in the appropriate sieve.
For sterilisation, additionally use a suitable packaging system, such as a sterile barrier system according to ISO 11607-x (e.g.: sterilisation paper, sterilisation containers).
Protect the packaging and contents from mechanical damage.

Sterilization

All NON-STERILE products can be sterilised with steam in an autoclave. The autoclaves must comply with EN 285 or EN 13060 with regard to validation, maintenance and inspection. The specifications of the manufacturer concerning loading and operation of the sterilizer must be followed exactly
The following procedure has been validated by Hofer Medical Solutions:

Procedures	Fractionated pre-vacuum process
Temperature	134 °C
Exposure duration	≥ 5 min
Drying time	≥ 20 min

If other procedures are used by the user, these must be validated by the user in accordance with EN ISO 17665-1. Ultimate responsibility for validation of sterilisation techniques and sterilisation equipment lies with the user.

Transport

Implants should not be transported or stored together with contaminated instruments, materials and / or equipment. Always handle the products with the necessary care. Take measures to protect against damage during transport. Carefully handle packaging and sterilization containers and protect them from damage or negative influences, e.g., mechanical or climatic type of effects.

Storage

Storage area with limited access that is climate-controlled, well ventilated, and dry and provides protection from dust, moisture, insects and parasites, as well as direct sun exposure. The maximum storage time depends on various factors such as packaging, storage methods, environmental conditions and handling. Users must define a maximum storage time for sterile products until use. Within this time, the products must be used or, if necessary, reprocessed (sterilised).

Disposal

The respectively applicable disposal guidelines of each hospital must be observed.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS REGARDING TEMPORARY METAL IMPLANT SYSTEMS

The following warnings, precautions, and adverse effects must be understood by the surgeon exactly and explained to the patient. These warnings do not include all adverse effects generally associated with a surgical procedure; rather, it contains considerations especially important for metal implant systems. The general surgical risks have to be explained to the patient before the actual surgery takes place.

Warnings

1) **The implantation of HOFER implants may only be carried out by surgeons with appropriate qualifications and experience in the field of orthopedics or traumatology** which corresponds to the state of the art in medical science in this field and which have appropriate practical training. The contents of this instruction leaflet and the operating instructions alone are not sufficient for performing the operations. Detailed, application-related information can be found in the corresponding medical manuals, the respective operating instructions or the training documents. In order to prevent possible complications, even surgeons experienced in orthopedics and traumatology should learn the necessary techniques from a surgeon who is familiar with the system or through specific training with practical training on the model.
2) **The surgeon and the clinical staff must be completely familiar with the medical and surgical aspects of the HOFER implants** and know about the mechanical and metallurgical restrictions as well as the combination and correct handling of surgical metal implants. These systems are neither intended as the only mechanism for support of the bony structures nor is this expected from the implant system. Regardless of the etiology that is the basis for deciding on the implantation of these systems, it is expected and required that bony fusion is planned and achieved. This kind of implant is more likely to fail if a bone mass is not used or pseudarthrosis develops. Without a solid biological support, one cannot expect that the implant systems fulfill their function for an uncertain duration: The implant systems can fail in different ways, e.g., failure of the bone-metal contact area, breakage of the implant, or bone fracturing. Due to anatomic limitations and despite modern surgical materials, metal implants are not guaranteed to be functional for an unlimited time.
3) **The HOFER system components may not be used together with components of other manufacturers** unless this is specifically mentioned.
4) **Selecting the correct implant size is extremely important.** The decision to choose a specific implant must be based, among others, on body weight, activity level, as well as the condition of the bone material of the patient. While the right choice can help improve the clinical outcome and minimize risks, the size and shape of the human bones place limitations on the implants concerning dimension, form and strength. The implantation method must be chosen according to the surgical state of art in this area.
5) **Implants can break if they are subjected to increased stress due to a delayed or not consolidated stiffening.** Implant systems serve to distribute the load to ensure a correct orientation up to the normal restoration of the fractured structure. If the healing process is delayed or does not happen at all, the implant can break due to fatigue of the material. Among others, the degree of stabilization, the weight-loading, and the activity level determine the lifespan of the implant. Notches, scratches, or intra-operative bending of the implant also can contribute to a premature failure. The patients should be informed completely about the risks of an implant failure.
6) **The use of different metals can cause corrosion.** A certain degree of corrosion appears on all implanted metals and alloys. The degree of corrosion on metal implants is generally very low due to the existence of passive surface coatings. If different metals such as titanium and high-grade steel come in contact with each other, the corrosion process for stainless steel is accelerated and the material is affected more strongly. The appearance of corrosion can accelerate implant failure due to material fatigue. This process also increases the quantity of metal components dissolved into the body. Internal fixative components such as rods, hooks, screws, plates etc., which come into contact with other metal objects, must consist of similar or compatible materials.
7) **Patient selection** When selecting patients for a certain implant system, the following factors can be extremely important for a successful treatment:
   A) <u>The body-weight of the patient</u>: An overweight or obese patient can stress the implant beyond its load carrying capacities, thus increasing the risk of implant failure and a failed operative treatment in consequence.
   B) <u>Profession or activity of the patient</u>: If the professional or private activities of the patient include heavy lifting, intense muscle strain, body rotations, repeated bending over, running, or manual labor, then these activities should be avoided until the complete bone healing has taken place. Even after healing is complete, the patient may not be able to resume these activities successfully.
   C) <u>Sensitivity, emotional illness, alcoholism, or drug and prescription medication abuse:</u> These circumstances can contribute to the patient ignoring certain restrictions and precautions required by the implant leading to implant failure or other complications.
   D) <u>Certain degenerative diseases:</u> In some cases, a degenerative disease at the time of the implantation procedure may have progressed so far that the

expected lifespan of the implant is significantly reduced, e.g., if osteoporosis is present, the necessary fixation may not be obtained. In such cases, orthopaedic aids can only delay the degeneration or achieve a temporary cessation.

E) Sensitivity to foreign bodies: Please note that there is no pre-operative test that can rule out completely the possibility of a sensitivity or allergic reaction. Even if the implant is in the body already for some time, the patient can exhibit an oversensitivity or allergic reaction.

F) Smoking: Smokers exhibit a higher rate of pseudoarthrosis with surgical procedures involving a bone implant. In addition, smokers are more likely to exhibit a diffuse degeneration of inter vertebral discs. A progressive degeneration of adjacent spine segments caused by smoking can lead to a later clinical failure (expressed by periodically appearing pain) even after an initially successful bone formation occurred and a clinical recovery was observed.

Precautions

1. **Do not reuse!**
   As a rule, surgical implants must never be reused. An explanted metal implant must not be reinserted. Even if the implant appears undamaged, it can have small defects and invisible overstressing that can lead to premature wear. This also applies to implants that had to be replaced interoperatively for whatever reason. **Preparation of an implant is not permitted if it has already been in patient contact or has been contaminated with blood, tissue or body fluids. In case of disregard, the manufacturer excludes any liability.** Consequences of reusing (the following list of consequences is exemplary and not intended to be complete)
   a. Implant failure
   b. Contamination
   c. Fit inaccuracies
2. **Proper handling of the implant is extremely important.** Metal implants should only be formed with dedicated instruments. The surgeon should avoid notching, scratching, or bending the product for several times during forming, as this may significantly reduce mechanical strength and thus lead to implant failure.
3. **Removal of the implant after healing.** If the system is not removed after completion of its intended use, the following complications may occur individually or collectively: (1) corrosion with local tissue reactions or pain; (2) change in implant position with resulting injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and/or fracture, making removal difficult or impossible; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) a possible increased risk of infection; and (7) bone loss due to stress shielding. The physician should carefully weigh the risks and benefits before removing an implant. After removal of the implant, adequate postoperative care should prevent recurrence of the fracture. In older or less active patients, the physician may choose not to remove the implant to eliminate the risks associated with a second surgery.
   In addition, it must be noted that steel may exhibit good ingrowth behavior. Especially in young patients, steel can form a bond with the bone. Therefore, if explantation is planned, the implant should be removed as soon as it is clinically safe to do so. Removal may be more difficult if the implant is damaged or the instruments not inserted properly or shows signs of wear.
4. **The patient must be informed exactly.** Post-operative clinical support and the ability of the patient to follow instructions are the most important aspects for a successful bone cure. The patient must be made aware of the implant limitations and receive instructions to avoid or limit physical activities, particularly lifting and rotary motions, as well as participation in sports activities. The patient must be aware of the fact that a metal implant is not as strong as a normal, healthy bone and that excessive strain and stress as well as noncompliance with the physical activity restrictions may lead to loosening, deformation, or breakage, especially in case of incomplete bone healing. Displaced or damaged implants can move and damage nerve tissue or blood vessels. An active or weakened patient or one suffering from dementia, who is unable to use supportive aids properly and as intended, is especially at risk during post-operative rehabilitation.
5. **Correct placement of the implant** When using the implants, it is important to note that the proximity of vascular and neurological structures to the site of implantation may increase the risk of serious or fatal bleeding and neurological damage when using this device. Severe or fatal bleeding may occur if the large vessels are eroded, punctured during implantation or damaged due to breakage or in case of migration of the implants after implantation, or if the vessels are pulsatile erosion of the vessels due to near apposition of the implants.
6. **Instruments.** The osteosynthesis implants may only be implanted with the instruments provided for this purpose.
7. **Check before use.** The implants must be checked for defects, scratches, notches, or other damage before implantation. Not appropriate implants must be removed.
8. **Interaction with imaging techniques:** Magnetic Resonance Imaging (MRI): Is not permitted.
9. **Pay attention to the details on the packing.**

Possible side effects (without any claim to completeness)

1. Deformation, bending or breaking of the implant (implant failure).
2. Loosening of the implant and possible loss of stability
3. Metal hypersensitivity or foreign body allergy.
4. Early or late infection.
5. Poor or delayed stiffening of fractures.
6. Reduction of bone density through stress shielding.
7. Pain, discomfort or unphysiological sensations due to implant presence as well as pain syndrome (CRPS).
8. Nerve damage due to surgical trauma or the presence of the implant. Neurological disorders, including bowel and / or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.
9. Bursitis.
10. Paralysis or movement restrictions.
11. Vascular damage due to surgical trauma or internal fixation. Vascular damage may lead to life-threatening or fatal bleeding. Incorrectly positioned implants near large blood vessels may erode these vessels and cause life-threatening bleeding in the late postoperative period.
12. Loosening of the screws with possible loosening of the implant and / or re-operation to remove the system.
13. Damage to the lymphatic vessels and / or exudation of lymphatic fluid.
14. Bone fracture.
15. Tendinitis and tendon rupture.
16. Loss of reduction.
17. Arthroses or pseudoarthroses.
18. Intra articular screws
19. Swelling
20. Sensory disturbances
21. Death.

Serious incidents that have occurred in connection with a Hofer-medical product must be reported to the national competent authority for medical device surveillance and to the manufacturer.

LIMITED GUARANTEE AND EXCLUSION OF LIABILITY: THE PRODUCTS OF HOFER ARE SUBJECT TO A LIMITED GUARANTEE FOR MATERIAL AND MANUFACTURING DEFECTS WHEN DELIVERED TO THE FIRST PURCHASER. FURTHER EXPLICIT OR IMPLIED GUARANTEES, INCLUDING THOSE CONCERNING MARKETABILITY AND SUITABILITY FOR A GIVEN PURPOSE, ARE EXCLUDED HEREBY.

IF THE PUBLISHED DOCUMENT IS OLDER THAN TWO YEARS, PLEASE REQUEST THE CURRENT PRODUCT INFORMATION FROM HOFER BY CALLING +43 3382 53388.

CONTRAINDICATIONS APPLICABLE TO ALL PRODUCT GROUPS

Absolute contraindications
- Possible or existing sensitivity to the material
- Application on the spine

Relative contraindications
- Infections or inflammations (acute, chronic, local)
- Decreased blood flow to the affected area
- Reduced bone stability for correct implant fixation
- Patients with little or no compliance in terms of adherence with postoperative rehabilitation recommendations
- Obesity
- For bone plates, cannulated screws: Patients with open epiphysial plates
- Inadequate soft tissue coverage
- Open soiled fractures with inadequate possibility of cleansing

Possible further contraindications are indicated in the respective product groups.

Product group	Intended use, indications and contraindications
ESIN (HSNesin & FGO) Basic UDI DI: 9009728ESIN6E 705-0xx-xxx-400	**Intended Use** Osteosynthesis implants are intended for stabilization and fixation of reduced bone fragments during natural fracture healing. This is to achieve healing of the fracture in the desired bone position. **Indications** • Diaphyseal fractures of the long tubular bones (in children and adolescents with open epiphysial plates) • Diaphyseal fractures of the long bones of the upper extremities (in adults) **Further absolute contraindications** • With leg fracture: Patient weight over 50 kg
Bone wires Basic UDI DI: 9009728WiresML 701-0xx-xxx-xxx	**Specific purpose Kirschner wires** • For closed reduction and fixation of a fracture using a Kirschner wire. **Specific purpose cerclage wires** • Cerclage wire is used to treat a fracture by wire wrapping as a stand-alone procedure. **Indications** • Reduction and fixation of metaphyseal fractures • Diaphyseal fractures and dislocations of the hand and foot bones • Temporary arthrodesis of small joints • Temporary intraoperative fixation of fracture fragments • Fractures of the musculoskeletal system • Closed / open fracture **Other absolute contraindication** • Twisting or strong inclination of the fracture (absolute) **Other relative contraindications** • Muscle, nerve, or vascular disease that compromises the affected limb • Local bone tumors • Systemic diseases and metabolic dysfunction • Severe malformations • Serious falls • Extensive physical activities and activities involving strong vibrations, where the implants are subjected to blows and/or excessive stress (e.g., heavy physical work, etc.)
Pectus excavatum Basic UDI DI: 9009728PSIJD 765-000-030-0xx	**Intended Use** Rib cage for supporting a raised sternum. **Indications** • Pain in the funnel chest area • Mental stress • Arrhythmias, heart valve insufficiency • Limited capacity • Haller Index > 3.2 **Absolute contraindication** • Preschool child • Renewed postoperative occurrence of manifestations of extensive rib calcification • Acne across large areas of the body

References to further documents (in the current version):

1) Product overviews for product-specific details
2) Operating instructions for implant specific information and surgical technique
3) Information on the processing of single-use metal osteosynthesis implants
4) The summary report on safety and clinical performance can be viewed in the European Medical Devices Database as of the release of the module: https://ec.europa.eu/tools/eudamed
   Note: The EUDAMED link will only be available once the European database for medical devices, EUDAMED, has been activated. Until activation, the summary report on safety and clinical performance is also available on request at the e-mail address quality@hofer-medical.com.

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Description of Hofer-specific symbols used for labeling:

To be used only by appropriately trained clinical personnel.

Before preparation, all packaging materials must be removed and disposed of.
Wash and disinfect before sterilizing as described in the current processing instructions.

CE 0483

Medical Device