INSTRUCTION FOR USE
STERILE PRODUCTS

STERILE R

OSTEOSYNTHESIS - IMPLANTS
Made of ISO 5832-2 Pure Titanium or ISO 5832-3 Titanium Alloy (Ti6Al4V)

For single use

GENERAL INFORMATION

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.

MATERIAL

The osteosynthesis implants are made of pure titanium or titanium alloys. The materials comply with standards ISO 5832-2 and ISO 5832-3 for titanium or titanium alloys. The material used is indicated by the packaging label.

Chemical composition Limit contents (percent mass fraction / %)		
Element	Titanium according to EN ISO 5832-3, grade 5 (Ti6Al4V)	Titanium according to EN ISO 5832-2, grade 2 (TiCP)
Aluminum	5.5 % to 6.75 %	-
Vanadium	3.5 % to 4.5 %	-
Iron	Max. 0.3 %	Max. 0.30 %
Oxygen	Max. 0.20 %	Max. 0.25 %
Carbon	Max. 0.08 %	Max. 0.08 %
Nitrogen	Max. 0.05 %	Max. 0.03 %
Hydrogen	Max. 0.015 %	Max. 0.0125 %
Titanium	Rest	Rest

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.

STORAGE INSTRUCTIONS

Original packaging, clean, dry, no direct sunlight. It must be ensured that the sterile barrier is not altered or damaged during 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.

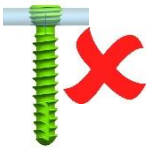
CORRECT LOCKING OF ANGULAR STABLE SYSTEMS INTEOS MONOAXIAL & POLYAXIAL SCREWS

Fig. 1

Correct: Locked

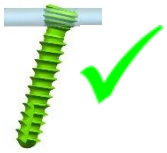
MONOAXIAL STABLE-ANGLE

Fig. 2



Incorrect: Unlocked

Fig. 3

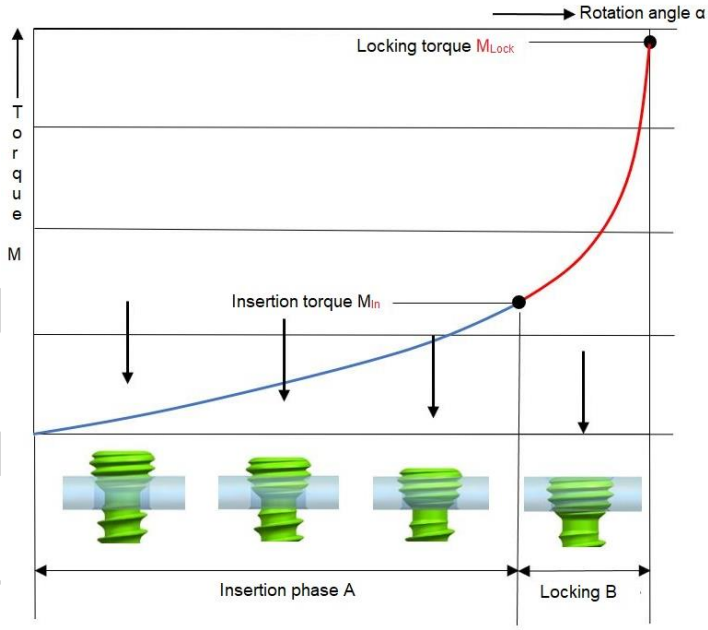


Correct: Locked

POLYAXIAL STABLE-ANGLE

Fig. 4

Incorrect: Unlocked



When inserting the screws, an increase in torque is noticeable when the screw head is screwed into the plate (see insertion phase A in the chart). Only then (area "B" in the chart) does the actual locking take place by firmly tightening the screws. The screws are only correctly locked when the screw head is largely flush with the plate surface (see area "B" in the chart or Fig. 1 and Fig. 3). If a screw head protrusion is visible or palpable (Fig. 2 and Fig. 4), retighten again until complete locking has been achieved. The strength of the angular stable locking in the deflected state is less than with undeflected screw connection. Multiple screwing and unscrewing of screws into and out of the bone should be avoided, as this may damage the bone substance and weaken the anchorage of the screw.

When using an optional torque limiter, the following tightening torques are applicable depending on the type of screw:

S
Screws size S, head diameter Ø 3.0 mm
Locking torque M_{LOCK} 0.7 Nm

M
Screws size M, head diameter Ø 4.0 mm
Locking torque M_{LOCK} 1.5 Nm

L
Screws size L, head diameter Ø 5.5 mm
Locking torque M_{LOCK} 2.0 Nm

STERILITY
The implants are delivered in sterile condition (radiation sterilization, symbol STERILE R on the label) and remain sterile as long as the sterile packaging (outermost peel pouch with label) is closed and undamaged. Each sterile package must be checked for integrity before use. The implants must not be used if the packaging is damaged or the expiry date has passed.

CLEANING AND DISINFECTION
The delivery of the implants is sterile, the implants do not need to be cleaned, disinfected or sterilized.

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 must 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. INTEOS screws must not be used as lag screws without a washer.
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) The body-weight of the patient: 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) Profession or activity of the patient: 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) Sensitivity, emotional illness, alcoholism, or drug and prescription medication abuse: These circumstances can contribute to the patient ignoring certain restrictions and precautions required by the implant leading to implant failure or other complications.
   D) Certain degenerative diseases: 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!**
   Surgical implants are intended for single use and must generally 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. 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. **Do not re-sterilise!**
   Implants that have been removed from their sterile packaging must not be reprocessed / sterilised. The manufacturer excludes all liability in the event of non-compliance.
3. **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.
4. **Implant removal after healing.** The following complications may occur alone or in combination if the system is not removed after completion of the planned use: (1) corrosion with local tissue reactions or pain; (2) change of the implant position with subsequent injuries; (3) danger of additional injuries due to post-operative trauma; (4) distortion, loosening, and/or implant failure complicating the implant removal or making it impossible; (5) pain, discomfort or unusual feelings due to the presence of the product; (6) a possibly increased risk for infections, and (7) bone loss caused by strain shielding. The physician should weigh risks and advantages carefully prior to removal of an implant. After the implant removal, a renewed bone fracture should be avoided through adequate post-operative support. With older or less active patients, the physician may forgo implant removal in order to exclude the risks associated with second surgery. Moreover, it should be noted that titanium generally is very well accepted by the body. Particularly in young patients, titanium implants can form a very strong bond with bones. If an implant removal is planned, this should be done as soon as safe based on clinical aspects. Removal may be more difficult if the implant is damages or the instruments are not used properly, or the implant shows signs of wear and tear.
5. **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.
6. **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.
7. **Instruments.** The osteosynthesis implants may only be implanted with the instruments provided for this purpose.
8. **Checking before use:** The integrity of the sterile packaging (outermost peel pouch with label) must be checked. In case of damage to the sterile packaging, e.g. missing vacuum, cracks or non-continuous sealing seam, the sterility of the implant cannot be guaranteed. In addition, the implants must be checked for defects, cracks, nicks or other damage before implantation. Implants that are not appropriate must be discarded.
9. **Interaction with imaging techniques:** Magnetic Resonance Imaging (MRI): Metal implants create image artefacts in their periphery that may interfere with the examination. In general, good compatibility should be expected. However, parameter constellations during the radiological examination, which are beyond the control of the manufacturer, also adversely affect this compatibility, which is why no binding statement may be made as to the compatibility. Throughout the duration, any possible temperature development due the implant should be closely monitored. In case of doubt, please contact the device manufacturer in advance.
10. **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 and OSTYS compression 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	Indications and contraindications
INTEOS Minifragment System Basic UDI-DI: 9009728Minifragment7T 716-13x-0xx-0xx-S 776-1xx-xxx-0xx-S	**Indications** • Fixation of fractures of small bones and small bone fragments of the hand
Straight Plate System / One-third Tubular Plates Basic UDI-DI: 9009728Straigt_PlatesSD 730-110-100-0xx-S HS GP Straight Plate 730-110-135-xxx-S HS GP 3.5 Straight Plate 730-100-135-xxx-S INTEOS HDRS 3.5 One-third Tubular Plate 730-100-100-0xx-S HDRS One-third Tubular Plate 730-112-135-0xx-S INTEOS HS GP 3.5 Straight Plate as av H-2 730-114-135-0xx-S INTEOS HS GP 3.5 Straight Plate as av H-4 770-190-030-001-S HS3.0 Washer nas	**Indications HS GP Straight Plate** • Diaphyseal fractures of the radius, ulna and fibula **Indications INTEOS HS GP 3.5, INTEOS HDRS 3.5 One-third Tubular Plate** • Diaphyseal fractures of the fibula and humerus **Indications HDRS One-third Tubular Plate, INTEOS HS GP 3.5 Straight Plate as av H-2** • Diaphyseal fractures of the radius, ulna, fibula and first metatarsus **Indications INTEOS HSGP 3.5 Straight Plate as av H-4** • Diaphyseal fractures of the humerus **Indications HS3.0 Washer** • Use insulated screws to prevent screws from sinking when applying compression in the bone. (Lag screws osteosynthesis)
INTEOS Radius System Basic UDI-DI: 9009728Radius_Ulna9S Radius Plates 775-11x-xxx-xxx-S 775-13x-xxx-xxx-S 775-140-xxx-xxx-S 775-150-xxx-xxx-S to 775-153-xxx-xxx-S 777-11x-xxx-xxx-S to 777-16x-xxx-xxx-S Ulna Plate 775-190-00x-00x-S 777-190-00x-0xx-S Fusion and Arthrodesis Plate 775-120-000-003-S 775-155-xxx-xxx-S 775-160-xxx-xxx-S	**Indications for Radius Plates** • Treatment of malposition or instability of wrist fracture at typical site (radius fracture loco typico) with and without joint involvement. • Corrective osteotomy in the area close to the joint in case of malposition after fracture / fracture healing of the wrist. **Indications for Ulna Plate** • Treatment of malposition or instability of wrist fracture at typical site (ulnar fracture) without joint involvement. (23-A1 fracture) • Corrective osteotomy in the area close to the joint in case of malposition after fracture / fracture healing of the wrist. **Indications for Fusion and Arthrodesis Plate** • Partial or complete arthrodesis of the wrist. **Further absolute contraindications** • A (mainly) ulnar-dorsally located and displaced joint, which may not be sufficiently reduced and fixed from the flexor side (Barton fracture, AO classification B2) • Open wrist fracture grade 2 or grade 3 with contamination of the wound without sufficiently cleansing or soft tissue coverage intra-operatively
Olecranon System Basic UDI-DI: 9009728ElbowER 730-135-xxx-xxx-S 730-145-xxx-xxx-S	**Indications** • Extra and intra-articular olecranon fractures • Pseudoarthrosis and osteotomies of the proximal ulna
INTEOS 2.5 Radius Head System Basic UDI-DI: 9009728ElbowER 777-18x-xxx-xxx-S	**Indications** • Fractures of the proximal radius • Osteotomies in the proximal radius
INTEOS 2.5 Coronoid System Basic UDI-DI: 9009728ElbowER 777-17x-xxx-xxx-S	**Indications** • Fractures of the coronoid at the proximal ulna

Product group	Indications and contraindications
Humerus Distal System Basic UDI-DI: 9009728ElbowER 770-120-00x-xxx-S to 770-122-00x-xxx-S 770-14x-xxx-xxx-S	**Indications** • Extra and intraarticular fractures, pseudoarthrosis and osteotomies of the distal humerus **Further relative contraindication** • Isolated shaft fractures
Humerus Proximal System Basic UDI-DI: 9009728HumerusCA 770-115-0xx-xxx-S 770-135-00x-xxx-S 770-136-00x-xxx-S 770-125-003-004-S 770-126-030-003-S	**Indications** • Fractures of the proximal humerus • Pseudarthrosis in the proximal humerus • Osteotomies in the proximal humerus **Further relative contraindication** • Isolated shaft fractures
Fibula System Basic UDI-DI: 9009728lower_limbsLF 798-110-10x-0xx-S 798-110-20x-0xx-S 798-110-21x-0xx-S	**Indications** • Extra and intraarticular fractures, pseudoarthroses and osteotomies of the distal fibula
Calcaneus System Basic UDI-DI: 9009728lower_limbsLF 731-100-00x-0xx-S 731-110-00x-0xx-S 731-111-x35-0xx-S	**Indications** • Extra and intraarticular fractures of the heel bone
Foot system Basic UDI-DI: 9009728lower_limbsLF 731-140-030-00x-S M-INTEOS Foot Straight Plate narrow 731-140-035-00x-S L-INTEOS Foot Straight Plate broad 731-141-00x-00x-S M-INTEOS Lisfranc 731-142-00x-00x-S M-INTEOS Lapidus plantar 731-143-00x-00x-S L-INTEOS Lapidus dors.med 731-147-00x-00x-S M-INTEOS Lapidus medial 731-144-x00-00x-S L-INTEOS Talonavicular 731-146-x00-00x-S M-INTEOS Talonavicular 731-145-xxx-00x-S M-INTEOS MTP-1	**Indications** • Fractures, osteotomies and arthrodesis of the foot
Tibia System Basic UDI-DI: 9009728lower_limbsLF 797-11x-xxx-0xx-S Distal tibial system 797-12x-xxx-0xx-S Proximal tibia system	**Indications distal tibial system** • Metaphyseal extra- and intra-articular fractures of the distal tibia **Indications for the proximal tibial system** • Metaphyseal extra- and intra-articular fractures of the proximal tibia
Clavicle Plating System Basic UDI-DI: 9009728ClavicleP2 Clavicle plates for clavicle shaft fractures 750-100-010-0xx-S 750-100-030-007-S 750-100-030-107-S 750-100-011-0xx-S 750-100-040-0xx-S 750-100-06x-0xx-S 750-100-06x-1xx-S Clavicle Plates with Hooks 750-100-1xx-0xx-S 750-100-11x-xxx-S 750-100-14x-xxx-S 750-100-17x-xxx-S Clavicle Plates, Lateral 750-100-015-005-S 750-100-05x-xxx-S	**Indications for the clavicle plates for clavicle shaft fractures** • Clavicle shaft fractures (in the middle third of the clavicle) • Osteotomy and pseudarthrosis of the clavicle **Indications for the INTEOS clavicle plates with hooks** • Lateral clavicle fractures: Neer type II or Jäger and Breitner type II • Dislocation of the acromioclavicular joint of the type: Tossy III or Rockwood III to V • Pseudarthrosis • Ligament reconstruction of the AC joint **Indications for lateral clavicle plates** • Lateral clavicle fractures • Pseudarthrosis (relative) • Ligament reconstruction of the AC joint (relative) **Other relative contraindications** • Stable lateral clavicle fracture • Tossy type I and II • Rockwood type I and II

Product group	Indications and contraindications
Clavicle HCP System Basic UDI-DI: 9009728Bone_NailC2 705-170-028-200-S 705-170-128-200-S	**Indications** • Fractures of the clavicular stem (in the area of the middle third of the clavicle) • Malunions and pseudarthroses of the clavicle shaft • HCPd - dynamic design: Simple, short oblique or transverse fractures in which no shortening is to be feared • HCPs - static design: Complex multi-fragment fractures or comminuted fractures where you want to set a length **Further relative contraindications** • Hard and tight clavicle with significant resistance during drilling and / or pin insertion
INTEOS Screws Basic UDI-DI: 9009728INTEOS_ScrewsM4 716-1xx-xxx-xxx-S	**Indication** • No independent indication, the indication is determined by the respective bone plates. **Indications in connection with the HS3.0 washer** • In the case of isolated screws, to prevent screws from being countersunk in the bone when compression is exerted. (Lag screw osteosynthesis).
OSTYS Screws Basic UDI-DI: 9009728OSTYS_Screws9H OSTYS screws Ø 3.0, Ø 3.5, Ø 4.0, Ø 4.5 717-1xx-030-0xx-S 717-1xx-035-0xx-S 717-1xx-040-0xx-S 717-1xx-045-0xx-S OSTYS screws Ø 6.5, Ø 7.3 717-1xx-065-0xx-S 717-1xx-073-0xx-S OSTYS compression screws 717-110-xxx-xxx-S 717-120-xxx-xxx-S 717-121-xxx-xxx-S 717-18-xxx-xxx-S OSTYS U-disk	**Indications for OSTYS screws Ø 3.0, Ø 3.5, Ø 4.0, Ø 4.5 and OSTYS compression screws** • Fixation of small bone fractures and small bone fragments **Indications for OSTYS screws Ø 6.5, Ø 7.3** • Fixation of fractures with large fragments
ESIN (HSNesin & FGO) Basic UDI-DI: 9009728ESIN6E 705-100-0xx-400-S 705-101-0xx-400-S 705-101-xxx-xxx-S 716-150-xxx-xxx-S	**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

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) 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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CE 0483

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Description of Hofer-specific symbols used for labeling:

To be used only by appropriately trained clinical personnel.

Indicates a medical product that has been sterilized by irradiation.

Indicates a medical product that should not be used if the packaging is damaged or opened.

Designates a medical product that must be protected against moisture.

Designates a medical product requires protection from light sources.

Indicates a medical product that must not be re-sterilized.

Indicates a medical device that must not be reused.

Indicates the date after which the medical product may no longer be used.

Indicates the date on which the medical product was manufactured.

Medical Device

Double peel pouch with inner protective pouch