Instructions for use
PG02 Implants Osteosynthesis

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Content

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PG02 Implants Osteosynthesis

PLEASE READ IMPORTANT PRODUCT INFORMATION CAREFULLY BEFORE ANY CLINICAL APPLICATION!

NON STERILE

CE 0483

SRN number: DE-MF-000007328

Dear customer!

With the purchase of this implant you will receive a high-quality product, the proper handling and use of which are described below. In order to keep hazards for patients and users as low as possible, we ask you to read and observe the instructions for use carefully.

Attention

Please read the information in these instructions carefully. Improper handling and care, as well as misuse can lead to premature wear and tear or risks for patients and users. Please also note the imprints on the packaging.

1 SCOPE

The scope of these instructions for use refers to the following products in our catalogues and brochures:

System:
DHS/DCS System
Large Fragment System
Small Fragment System
Minifragment System
Screw system
Locking Schmalfragment
Locking Großfragment

2 INTENDED PURPOSE / INDICATION / MATERIAL

2.1 Purpose

Description and specifications of the product including intended purpose, indication(s), contraindication(s) and warnings, the intended patient group and the disease condition to be diagnosed/treated/monitored.

2.2 Indications

2.2.1 DHS/DCS Implants

DHS

- Pertrochanteric fractures type 31-A1 and 31-A2
- Intertrochanteric fractures type 31-A3
- femoral neck fractures 31-B
- Subtrochanteric fractures

DCS

- Proximal femur: Widely proximally localized, purely subtrochanteric fractures of type 32-A and 32-B
- Distal femur: fractures of type 33-A (extra-articular, supracondylar) and fractures of type 33-C (purely articular fractures)

2.2.2 Minifragment System

Minifragment System (plate screws) 1.5, 2.0, 2.7

- Fractures of middle and distal phalanges and tarsal bones
- Fractures of the metacarpal and metatarsal bones
- Osteotomies and arthrodesis of the hand and foot
- Fractures of the distal radius (double-plate technique)

Minifragment System (screws) 1.5, 2.0, 2.7

- Tensile screw osteosynthesis of metacarpal and metatarsal fractures, as well as small fragments. This washer can be used to prevent the head of a screw from splitting the cortex and sinking into the bone.

Condylar plates 1.5, 2.0, 2.7

- 1.5, 2.0 Osteotomies near metacarpophalangeal (MP) or proximal interphalangeal (PIP) joints
- 2,7 Fractures of the metacarpal and metatarsal bones near the joint

Quarter pipe plates

- Tension strapping plates for fractures of the metacarpal and metatarsal bones

T-plates

- Fractures at the distal or proximal end of the phalanx

2.2.3 Small Fragment System

3.5 third-tube plates

- Fractures in bones of smaller size, for example, fibula, humerus and ulna.

3.5 clover plates

- Distal tibia in comminuted fractures to support their midside
- Proximal humerus in comminuted fractures of the femoral head

3.5 LC-DCP plates and DCP plates

- Fracture fixation and fixation after osteotomies, improper healing, pseudarthrosis, especially of the distal radius, proximal and distal tibia, proximal humerus and clavicle.

3.5 reconstruction plates

- Pelvic margin fractures
- Fractures of the ilium/iliac scoop
- Acetabular fractures

3.5 T-plates at right angles

- Fractures of the volar side of the distal radius

3.5 T-plates obliquely angled
- Fractures of the dorsal side of the distal radius

3.5 clavicular plates
- Clavicular fractures

3.5 calcaneal plate
- Calcaneal fractures

2.2.4 Large Fragment System

4.5 half-pipe plates
- Fractures and osteotomies of smaller bones, e.g., humerus, radius, ulna, clavicle, fibula, tibia, and pelvis

4.5 LC-DCP plates and DCP plates
- Fractures and osteotomies of large bones, such as the femur, tibia, and humerus

4.5 condylar support plates
- Support of multifragmentary distal femoral fractures
- Supracondylar fractures
- Intra-articular and extra-articular condylar fractures
- Incorrect healing and pseudarthrosis of the distal femur
- Periprosthetic fractures

4.5 proximal tibial plates
- Fractures of the proximal tibia, failed fusions

4.5 Lateral tibial head support plate
- stabilization of fractures of the proximal tibia, proximal shaft fractures,
- Metaphysis fractures, intra-articular fractures

Condylar plates 95°
- Fractures and revisions of the proximal and distal third of the femur in patients with completed skeletal growth.

Angle plates 130°
- Fractures and revisions of the proximal third of the femur in patients with completed skeletal growth.

Osteotomy plates adults 87°, 95°, 100°, 110°
- Hip plate osteotomies on the proximal femur in patients with completed skeletal growth.

Osteotomy plates for infants and adolescents 80°, 87°, 90°, 100°, 115°
The system is indicated for use in babies, toddlers, children, adolescents and adult patients of small stature.

Specific indications are:
- Intertrochanteric derotation and variation osteotomies

Osteotomy plates
- Intertrochantäre Valgus-Osteotomien
- Femural neck and pertrochanteric fractures

2.2.5 Screw System

Ø 4.5 Malleolar screws
- Malleolar fractures

Ø 3.0 screw cannulated

Fixation of fractures of the forearm, hand and foot, e.g.:

- Fractures and arthrodesis of carpal and metacarpal bones
- Fractures of distal radius and radial head
- Metatarsal fractures

Ø 3.5 Screw cannulated

Fixation of fractures of small fragments, e.g.:

- Wrist fractures
- Metacarpal and metatarsal fractures and fixation of osteotomies of metacarpal and metatarsal bones
- Tarsal bone fractures
- transcondylar humeral fractures in children

Ø 4.5 Screw cannulated

Fixation of fractures of medium-sized fragments, for example:

- Malleolarfrakturen
- Drumstick-Tibial-Frakturen
- Fractures of calcaneus and talus
- Tibiaplateaufrakturen
- Hand and tarsal bone arthrodesis

Ø 6.5 / Ø 7.0 screw cannulated

Fixation of fractures of large fragments, for example:

- Femural neck fractures
- intercondylar femoral fractures
- Epiphyseolysis capitis femoris
- Sprunggelenkarthrodese
- Dislocations of the sacroiliac joint

2.2.6 Locking Narrow Fragment

3.5 mm T-plates / radius plates

- Fixation of complex intra- and extra-articular fractures
- Fractures of the distal radius and other small bones
- distal radius fracture

3.5 mm reconstruction plates

- Fractures in the pelvis and hip area
- Fractures of the distal humerus, clavicle, or calcaneus

3.5 mm third-tube plates

- Fractures of smaller bones, such as the fibula, humerus, ulna.

3.5 mm straight plates

- Fractures of smaller bones such as ulna, radius, and humerus
- periprosthetic fractures

3.5 mm distal humeral plates

- Distal humeral fractures

3.5 mm proximal humeral plates

- Proximal humeral fractures

3.5 clavicle plate

- Clavicular fractures

3.5 Olecranon plate

- Fractures of smaller bones such as olecranon and ulna

3.5 calcaneal plate
- Calcaneal fractures

3.5 Fibula plate
- Fractures of the fibula, the fibulas

3.5 Metaphyseal plate
- extra-articular fractures of the metaphyseal area, which can extend into the shaft area
- Fractures of the distal tibia, distal / proximal humerus, distal fibula

3,5 Tibiaplatte, distal, proximal
- Fractures of the tibia, the tibial confinement

2.2.7 Locking large fragment

5,0 DHS-/DCS-Platte
- femoral neck fractures
- supracondylar fractures

5.0 Straight plates
- Fractures of larger bones such as humerus, tibia, femur
- periprosthetic fractures

5.0 femoral plate
- supportive multi-fragment fractures of the femur

5.0 Metaphyseal plate
- Fixation to support multi-fragmentary metaphyseal fractures

5.0 Tibial plate, distal, proximal
- Fractures of the tibia, the tibial confinement

5.0 T-plates
- Fixation of metaphyseal fractures
- proximal humeral fractures,
- Fractures of the medial tibial plateau
- Fractures of the distal tibia with associated shaft fractures

2.3 Contraindications

2.3.1 General contraindications

- Insufficient bone substance (e.g. severe osteoarthritis)
- Patients with metal allergies or hypersensitivity reactions
- Patients with circulatory disorders and coagulation disorders
- Large physical and shock-related activities in which the implants are subjected to blows and/or excessive stress (e.g. heavy physical work, etc.).
- Patient who is mentally unable to understand and follow the doctor's instructions
- Patient with acute chronic infection
- Wound healing disorders caused by type 2 diabetes mellitus (macroangiopathy)

2.3.2 Product-specific contraindications

DHS/DCS Implants

Do not use DHS in cases with high incidence of:

- Sepsis
- Malignant primary or metastatic tumors
- Material hypersensitivity
- Compromised vascularity

Do not use DCS for:

- Pertrochanteric fractures or trochanteric fractures with subtrochanteric enlargement (31-A3)

2.4 Undesirable side effects / complications / risks

In many cases, complications are caused by the surgical procedure rather than the implant.

General undesirable side effects, complications and risks

- delayed or non-healing of the fracture
- Deformities
- Bone infections
- significant, sometimes permanent restriction of movement of adjacent joints
- Pain or discomfort due to the insertion of the implant (bone plates and bone screws)
- Primary as well as secondary, superficial and/or deep infection / sepsis
- Hematomas and reduced wound healing
- Edema or swelling, possible compartment syndrome
- Allergic reactions to the implant material
- Clinical failure due to e.g. incorrect assembly technique of the bone plates and screws with the consequence of loss of fixation; Excessive movement at the fracture site: failure of the bone plates and screws
- Loosening or fracture of screws and bone plates including unintentional injury to the patient or surgical staff due to the pointed screw end
- Re-operation: a component or the entire device must be replaced
- Excessive surgical bleeding or muscle-tendon injury
- intrinsic risks associated with anesthesia
- Pseudarthrosis
- Fracture of the regenerated bone fracture or through a hole after metal removal (plates, screws)
- abnormal growth plate: development in patients who are not fully grown• loss of bone mass due to "stress shielding"
- Bone sequestration secondary: too fast drilling of the bone cortex, with heat build-up and bone necrosis
- Thrombosis, thrombophlebitis, pulmonary embolism, bruising and nonvascular necrosis
- In case of insufficient coalescence of the fracture, a loss of anatomical layers may occur
- Penetration of the screws through the bone (most often in conjunction with osteoporotic bone).
- Penetration of the screw through the joint (usually in connection with small-angled plates or an impairment of the sliding of the screw as well as unsuitable plate fixation)
- Injuries to the growth plates due to trauma during surgery or as a result of the length or location of a bone screw

Treatment-related adverse side effects, complications and risks

- Ache
- Pseudarthrosis
- Failure of the implants
- Infections
- Re-fractures
- Injuries to tissues / organs / nerves
- Lack of healing
- Movement restrictions
- Necrosis
- Wound infections
- Nerve damage
- Foreign bodies in the patient
- Malunion of the bone
- Arthritis
- Allergic reactions to materials
- Swelling / edema
- Irritation
- Haematoma
- Joint dislocation
- Bleedings
- Stiffness
- Fistulas
- Sepsis
- Scarring
- Itching sensation
- Pneumonia
- Fever
- Cysts

Product-related undesirable side effects, complications and risks

- Adverse events with no identified problems
- Rupture of the implants
- Incompatibility of implants
- Migration of implants
- Lack of information about the product
- Material deformation
- Loosening of implants
- Manufacturing
- Packing errors
- Implants corroded
- Mechanical problems
- Difficult to remove
- Contaminated implants
- Off-Label Uses
- Material: Discoloration
- Cracks on the implant
- Lack of or incorrect labeling of the implants
- Sharp edges on the implant
- Missing components
- Lack of biocompatibility
- Self-incision of bone screws faulty
- Death of the patient

- Muscular stiffness

2.5 Warnings

- The products may only be used with the appropriate components and instruments:
- Make sure that the screws are tight in the respective instrument. When implanting, make sure that there is sufficient axial pressure over the screws. Otherwise, there is a risk of mechanical damage.
- Excessive bending of the bone plates can lead to damage to the implants and/or premature failure of the plates.
- Multiple bending of the bone plates can lead to damage to the implants and/or premature failure of the plates.
- Bending the locking systems is prohibited. These systems are anatomically predefined and a bend would destroy the locking between plates and screws.
- Reuse of implants is absolutely prohibited (single use).

Do not reuse

Failure to observe the restriction (single-use product) can have serious consequences for the patient, e.g.

1. Implant failure (e.g. fracture)
2. Lack of healing

Conditions that can affect the success of the operation:

- Of utmost importance is the correct selection of implant components - the appropriate type of implant as well as the size. Implants must be adapted to the individual patient. The use of the largest possible implant as well as the correct positioning prevent bending, breaking, cracking and loosening of the implant.
- Care must be taken to ensure that the forces to be transmitted by the implants are kept low by choosing the right biomechanics.
- In the case of fractures and osteotomies, the implants are subjected to increased loads. The period with only a very small load until the fracture grows together stably must be chosen for a sufficiently long time.
- In some fractures and osteotomies, the implants are exposed to particularly high loads, as the muscle forces do not act evenly, thus greatly reducing the chance of healing due to bending or even breaking implants. Additional precautions and internal and external proppants are required to increase the stability of the fracture and minimize stress on the implant until a solid fracture is established by X-ray examinations.

Before using these implants, the surgeon is required to perform the following Recommendations and notes to take note of:

- The thread of the screw must not come to rest in the fracture line. The correct selection of the screw length is important, as the screws must be completely fixed in the bone in order to allow telescopic movement in the event of resorption of the fracture surface.
- Only implants made of the same systems and the same materials may be used together.
- The implants must not come into contact with objects that could damage their surface. They may not be mechanically processed or otherwise altered, unless the design and surgical technique expressly provide for this.
- Surgical technique: The rules of art and science as well as scientific publications are decisive. A surgical description can never be complete and include all the risks and complications that need to be considered. Information regarding the surgical technique is available on request. During the procedure, the surgeon must familiarize himself with the implants, instruments and corresponding techniques.

2.6 Restrictions

The product group is not intended to be used on the central nervous/circulatory system.PG02 Implants Osteosynthesis

2.7 Patient population

No specific patient populations. The products should be used taking into account the intended purpose, indications and contraindications, as well as taking into account the anatomy and state of health of the patient. The attending surgeon decides depending on the circumstances.

2.8 User and field of application

The products are used by specialists in orthopedics and trauma surgery.
The attending surgeon is responsible for the correct selection of patients, for the necessary training, selection and placement of implants on the basis of sufficient experience, as well as the decision to leave or remove implants postoperatively.

2.9 Clinical benefits

The clinical benefit of the product group is, when used in accordance with the valid instructions for use and recommended techniques, stabilization, reconstruction of bone fractures. The product group facilitates healing and restores the anatomical relationships and functional properties.PG02 Implants OsteosynthesisPG02 Implants Osteosynthesis

2.10 Capability characteristics

Digimed Medizintechnik has proven the performance and safety of the products and that it is a state-of-the-art medical device for osteosynthesis for stabilization, reconstruction of bone fractures when used in accordance with the instructions for use, recommended techniques and labeling.PG02 Implants Osteosynthesis

2.11 Materials

- Implant steel 1.4441 acc.ISO 5832-1 or ASTM F138
- Titan Grade 5 - ELI (Ti6Al4V) gem. ASTM F136 oder ISO 5832-3
- Titanium Grade 2 according to ASTM F67 or ISO 5832-2

2.12 Attention

Instruments, and in particular implants, may only be used by persons who have been specially trained or instructed to do so. For implantation and explantation, it is necessary to use appropriate instruments. (see "Instruments for introduction and explantation"). Explantation of the implants is recommended after the restoration of the patient's bone quality.

3 MRI INSTRUCTIONS

The implants have been subjected to EMC testing and fully meet the requirements. There are no impairments to function. safety and performance and are therefore also suitable for MRI.

4 POSTOPERATIVE CARE

- Postoperative instructions to patients as well as proper nursing care are of great importance, an earlier weight load increases the stress on the implant and can lead to breakage, bending or loosening. Early loading can be considered if there is a stable fracture with good bone contact.
- The final decision to remove the implant is made by the surgeon. The implants should be removed when they are no longer needed as an aid to healing, and such a step is possible and practical for the patient.

5 LIFESPAN / EXPLANTATION

5.1 Lifetime

No indication of durability or functional restriction is given for implants delivered non-sterile after manufacture, if they are stored properly. The products are intended for single use.

5.2 Explantation

When a surgically stabilized situation on the musculoskeletal system is "ripe" for material removal depends on several factors and should subsequently be divided into groups. In general, the attending physician/surgeon decides together with the patient when and if an explant takes place. The implants are designed for long-term implantation.

Localization	Type of osteosynthesis	Recommendation period in months
Ventral/dorsa cervical spine	Screw/plate systems	-
BWS/LWS dorsal	Screw/rod systems	9–12
BWS/LWS ventral	Screw/rod systems	-
Pelvis	Rekonstruktionsplatten winkelstabil	9–12
Klavikula	Plattenosteosynthese, ESIN/TEN	6
AC joint	Zuggurtung Hakenplatte	1,5–2 3–4

Upper arm proxima	Plattenosteosynthese winkelstabil	9–12
Upper arm shaft area	Plattenosteosynthese	18
Upper arm distal	Plattenosteosynthese	12
Olekranon	Zuggurtung	9
Forearm	Plattenosteosynthese	18–24
distal radius (dorsal and palmar)	Plattenosteosynthese winkelstabil	12
Hand	Plate systems, transfixing wires, screw systems	6–9 1,5–3
proximal/koxal Femur	DHS, PFN	12–18
Femur Schaftbereich	Plattenosteosynthese Marknagel	12–24 12–18
Femur distal	Tension strapping, angle-stable systems	12
Tibiakopf	Plattenosteosynthese winkelstabi	12–18
Lower leg shaft area	Marknagel Plattenosteosynthese	18–24
Tibial drumstick	Plattenosteosynthese winkelstabil	12
Ankle	Tension strapping, third-tube plate, adjusting screw	6–12 1,5
Embankment	kanülierte Kleinfragmentschrauben	12–18
Kalkaneus	Rekonstruktionsplatte winkelstabil	10–12

6 INSTRUCTIONS FOR USE AND SAFETY

The products must be inspected for defects, cracks, notches or other damage before use. Damaged products must be sorted out.

The products are delivered in a non-sterile condition and must be completely cleaned, disinfected and sterilized by the user before being used for the first time.

6.1 Surgical techniques

The respective recognized surgical techniques apply. The surgeon must undergo further training in accordance with the recognised surgical techniques. For surgical techniques, the specialist literature AO Principles of Fracture Management can be consulted.

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7 PATIENT BEHAVIOUR

The patient should be advised that the safety and lifespan of the implant depend on his behavior and activity. Therefore, any form of competitive and competitive sports in which the implants are affected is contraindicated.

8 CORRECT SELECTION OF IMPLANTS

The choice of implants is made taking into account the patient-specific characteristics, such as the type of fracture / injury and the condition of the patient's bone material. The implantation method should be chosen in accordance with the state of the art in this field. Errors in the selection of the implant can lead to premature clinical implant failure. The use of the right components allows for a sufficient blood supply and results in a stable fixation, whereas a wrong decision can lead to loosening,

bending or fracture of the implant and/or bone, among other things. In general, the implants are designed for temporary use.

9 COMBINATION PRODUCTS & ACCESSORIES

9.1 DHS/DCS System

DCS/DHS plates:

- DHS plates 17-000-2503 to 17-000-5014
- DCS Supracondylar Plates 17-000-9504 to 17-000-9522
- DHS plates, short cylinder 17-001-3503 to 17-001-3510

DCS/DCS screws:

- DHS pull screws 17-000-0050 to 17-000-0145
- DHS Compression Screw 17-000-0036
- Cortical screws Ø 4.5 mm 17-064-0014 to 17-064-0140
- 6.5mm cancellous screw 16 mm thread 17-074-1025 to 17-074-1140
- 6.5mm cancellous screw 32 mm thread 17-074-3040 to 17-074-3150
- 6.5mm Cancellous Screw Full Thread 17-074-0020 to 17-074-0130

9.2 Minifragment System

Flat tyre:

- Ø 1.5 mm; mini plate, straight 17-010-0003 to 17-010-0050
- Ø 1.5 mm; T-plates 17-010-0339 to 17-010-0349
- Ø 1.5 mm; Condylar plates 17-010-1106 – 17-010-1206
- Ø 1.5 mm; H-plate 17-010-8004
- Ø 2.0 mm; Mini DCP plates, straight 17-011-0003 – 17-011-0048

Screw:

- 1.5 mm cortex screw 17-060-0006 – 17-060-0024 - 17-060-0506 – 17-060-0524
- 2.0 /4.5 mm washers 17-088-0004 – 17-088-0019

Flat tyre:

- Ø 2.0 mm; Mini DCP plates, straight 17-011-0003 – 17-011-0048
- Ø 2.0 mm; L-plate, 90° left 17-011-0102
- Ø 2.0 mm; L-plate, 90° right 17-011-0202
- Ø 2.0 mm; L-plate, oblique left 17-011-0402
- Ø 2.0 mm; T-plate 17-011-0302
- Ø 2.0 mm; L-plate, oblique right 17-011-0502
- Ø 2.0 mm; compression plates, straight 17-011-0022
- Ø 2.0 mm; T-plates 17-011-0338 – 17-011-0349
- Ø 2.0 mm; H-plate 17-011-0804
- Ø 2.0 mm; Mini DCP plates 17-011-1004 - 17-011-1020
- Ø 2.0 mm; Mini DCP plates 17-011-1014 – 17-011-1030
- Ø 2.0 mm; Adaptation plate 17-011-1420
- Ø 2.0 mm; LC/DCP Mini Plates 17-011-2004 – 17-011-2020
- Ø 2.0 mm; Condylar plates 17-011-1106 – 17-011-1206

Screw
- 2.0mm Cortical Screw 17-061-006 – 17-061-0038

Flat tyre:
- Ø 2.7 mm; DCP compression plates 17-012-002 – 17-012-0014
- Ø 2.7 mm; LC/DCP compression plates 17-012-2002 – 17-012-2014
- Ø 2.7 mm; L-plate, 90° right 17-012-0203
- Ø 2.7 mm; L-plate, 90° left 17-012-0103
- Ø 2.7 mm; T-plates 17-012-0303 – 17-012-0308
- Ø 2.7 mm; L-plate, oblique left 17-012-0403
- Ø 2.7 mm; L-plate, oblique right 17-012-0503
- Ø 2.7 mm; Multifragment plate 17-012-0907
- Ø 2.7 mm; straight 17-051-005 – 17-051-0024
- Ø 2.7 mm; quarter tube plates 17-014-003 – 17-014-0010
- Ø 2.7 mm; Condylar plates 17-012-1106 – 17-012-1206

Screw:
- Ø 2.7 mm Cortex Screw 17-062-0006 – 17-062-0040 (standard)
- Ø 2.7 mm Cortex screw 17-062-0506 – 17-062-0540 (self-bleed)

9.3 Small Fragment System

Flat tyre:
- 3.5 mm; DCP compression plates 17-020-0002 – 17-020-0022
- 3.5 mm; third tube plates 17-022-0002 – 17-022-0014
- 3.5 mm; LC/DCP compression plates 17-020-2004 – 17-020-2012
- 3.5 mm; third tube plates with collar 17-022-1002 – 17-022-1012
- 3.5 mm; Reinforced LC small fragment plates 17-024-2007 – 17-024-2016
- 3.5 mm Reconstruction Plate 17-050-0003 – 17-050-0022
- 3.5 mm Reconstruction Plate Curved 17-050-0106 – 17-050-0118
- 3.5 mm; T-plates, right angle 17-026-0333 – 17-026-0364
- 3.5 mm; cloverleaf plates 17-028-0003 – 17-028-0012
- 3.5 mm; T-plates, oblique 17-026-0933 – 17-026-0953
- 3.5 mm; Clavicula Plate 17-028-1104 – 17-028-1106 / 17-028-1204 – 17-028-1206
- 3.5 mm; Kalkaneal Plates 17-029-0060 – 17-029-0070

Screw
- Ø 3.5 Cortical screw 17-063-0010 – 17-063-0120 (steel standard)
- Ø 3.5 Cortical screw 17-063-0510 – 17-063-0620 (steel self-cut)
- Ø 4,0 Cancellous screw 17-072-0010 – 17-072-0060
- ø 3.5 mm screw cannulated full thread 17-080-0010 – 17-080-0050 (steel)
- ø 3.5 mm screw cannulated half thread 17-080-2010 – 17-080-2050 (steel)

9.4 Large Fragment System

Straight plates:

- 4.5 mm; DCP compression plates, narrow 17-030-0002 – 17-030-0024
- 4.5 mm; LC/DCP compression plates, narrow 17-030-2002 – 17-030-2016
- 4.5 mm; DCP compression plates, wide 17-031-0002 – 17-031-0026
- 4.5 mm; LC/DCP compression plates, wide 17-031-2006 – 17-031-2018
- 4.5 mm; half-tube plates 17-032-0002 – 17-032-0012
- Wide extension plates 8 holes 17-046-0125 – 17-045-0165
- Wide extension plates 10 holes 17-047-0180 – 17-047-0250
- Narrow extension plates 8 holes 17-045-0125-17-045-0175

Screw:

- Ø 4.5 cortex screw 17-064-0014 – 17-064-0058 (steel standard)
- Ø 4,5 cortex screw 17-064-0514 – 17-064-0558 steel self-gate)
- Ø 6,5 Cancellous screw full thread 17-074-0020 – 17-074-0130
- Ø 6,5 Cancellous screw 16 mm 17-074-1025 – 17-074-1140
- Ø 6,5 Cancellous screw 32 mm 17-074-3040 – 17-074-3150

Reconstruction plates:

- 4.5mm reconstruction plate straight 17-052-003 – 17-052-0016

Screw:

- Ø 4.5 cortex screw 17-064-0014 – 17-064-0058 (steel standard)
- Ø 4.5 Cortical screw 17-064-0514 – 17-064-0558 (steel self-bleed)

Special plates:

- 4.5 mm; L-support plates 17-034-0603 – 17-034-0610 / 17-034-0703 – 17-034-0710
- 4.5 mm; large T-plates 17-034-0303 – 17-034-0312
- 4.5 mm; T-support plates 17-034-0804 – 17-034-0808
- 4.5 mm; distal tibial plates, medial 17-044-0105 – 17-044-0115 / 17-044-0205 – 17-044-0215
- 4.5 mm; spoon plates 17-039-0005 – 17-039-0006
- 4.5 mm; distal femoral plates, lateral 17-041-0105 – 17-041-0113 / 17-041-0205 – 17-041-0213
- 4.5 mm; Condylar support plates, distal 17-040-0107 – 17-040-0115 / 17-040-207 – 17-04-0215
- 4.5 mm; proximal tibial plates, lateral 17-042-0105 -17-042-0115 / 17-042-0205 – 17-042-0215
- 4,5 mm; Tibiakopf-Abstützplatten, lateral / 17-043-0105 – 17-043-0113 / 17-043-0205 – 17-043-0213

Screw:

- Ø 4.5 cortex screw 17-064-0014 – 17-064-0058 (steel standard)
- Ø 4,5 cortex screw 17-064-0514 – 17-064-0558 steel self-gate)
- Ø 6,5 Cancellous screw full thread 17-074-0020 – 17-074-0130
- Ø 6,5 Cancellous screw 16 mm 17-074-1025 – 17-074-1140
- Ø 6,5 Cancellous screw 32 mm 17-074-3040 – 17-074-3150

Blade plates:

- 3.5 mm; Blade plates, 3 holes 17-053-0012 – 17-053-0114
- 4.5 mm; Blade plates for children, 3/*4 holes 17-053-2012 – 17-053-3219
- 3.5 mm; Children's Osteotomy Plates 17-053-1012 – 17-053-1013
- 4.5 mm; Osteotomy plates for adolescents, holes 17-054-0012 - 17-054-0116
- Condylar plates small stature, 95° 17-054-0540 – 17-054-0970
- Osteotomy blades plates, 87°, 4 holes 17-055-0002 – 17-055-0209
- Osteotomy blades plates, 100°, 4 holes 17-055-1004 – 17-055-1006
- Angle plates small-stature, 130° 17-054-2450 – 17-054-2980
- Osteotomy blades plates, 110° 4 holes 17-055-2007 – 17-055-4016
- Angle blade-plates, 130° 17-056-0450 – 17-056-1290
- Condylic blade plates, 95° 17-056-2550 – 17-056-3880

Screw:

- Ø 3.5 Cortical screw 17-063-0010 – 17-063-0120 (steel standard)
- Ø 3.5 Cortical screw 17-063-0510 – 17-063-0620 (steel self-cut)
- Ø 4,0 Cancellous screw 17-072-0010 – 17-072-0060

- ø 3.5 mm screw cannulated full thread 17-080-0010 – 17-080-0050 (steel)
- ø 3.5 mm screw cannulated half thread 17-080-2010 – 17-080-2050 (steel)
- Ø 4.5 cortex screw 17-064-0014 – 17-064-0058 (steel standard)
- Ø 4,5 cortex screw 17-064-0514 – 17-064-0558 steel self-gate)
- Ø 6,5 Cancellous screw full thread 17-074-0020 – 17-074-0130
- Ø 6,5 Cancellous screw 16 mm 17-074-1025 – 17-074-1140
- Ø 6,5 Cancellous screw 32 mm 17-074-3040 – 17-074-3150

9.5 Screw system

4.5 MALLEOLAR screws
- Ø 4.5 mm Malleolar Screws 17-078-0020 – 17-078-0080
- Washer 17-088-0013

3.5 MM SCREW CANNULATED
- ø 3.5 mm screw cannulated full thread
  - 17-080-0010 – 17-080-0050 (steel)
  - 17-180-0010 – 17-180-0050 (titanium)
- ø 3.5 mm screw cannulated half-thread
  - 17-080-2010 – 17-080-2050 (Stahl)
  - 17-180-2010 – 17-180-2050 (Titan)
- Washer
  - 17-088-0007 (Stahl)
  - 17-188-0007 (Titan)

4.5 MM SCREW CANNULATED
- Ø 4.5 mm screw cannulated full thread
  - 17-081-0010 – 17-081-0050 (Stahl)
  - 17-181-0010 – 17-181-0050 (Titan)
- Ø 4.5 mm screw cannulated half-thread
  - 17-081-2020 – 17-081-2072 (Stahl)
  - 17-181-2020 – 17-181-2072 (Titan)
- Washer
  - 17-088-0010 (Stahl)
  - 17-188-0010 (Titan)

6.5 MM SCREW CANNULATED
- Ø 6.5 mm Screw cannulated 16 mm
  - 17-082-1025 - 17-082-1120
- Washer
  - 17-088-0013 (Stahl)

7.0 MM SCREW CANNULATED
- Ø 7.0 mm screw cannulated 16 mm thread
  - 17-083-1030 – 17-083-1130(Stahl)
  - 17-183-1030 – 17-183-1130 (Titan)
- Ø 7.0 mm screw cannulated 32 mm thread
  - 17-083-3045 – 17-083-3130 (Stahl)
  - 17-183-3045 – 17-183-3130 (Titan)
- Ø 7.0 mm screw cannulated full thread
  - 17-183-0025 – 17-183-0130 (Titan)
- Washer
  - 17-088-0013 (Stahl)
  - 17-188-0013 (Titan)

9.6 Locking Schmalfragment

Plates:

- Titanium T-Plate Oblique Angled 3.5 mm Locking Plate 90-0520-003 – 90-0530-006
- Titanium Anatomical T-Plate Right Angled 3.5 mm Locking Plate 90-0590-033 – 90-0590-064
- Titanium Radius Plate, Prebent Anatomical 3,5mm Locking Plate 90-0540-003 – 90-0550-004
- Titanium Radius Plate Prebent 3,5mmLocking Plate 90-0541-002 – 90-0551-006
- Titanium Plate 3.5 mm small, straight Combi Hole Low Touch Locking Plate 90-0104-059 – 90-0112-189
- Titanium Reconstruction Plate 3.5 mm, straight Standard Hole Locking Plate 90-0500-005 – 90-0500-022
- Titanium Reconstruction Plate 3.5 mm, straight without Combi Hole Locking Plate 90-0510-005 – 90-0510-022
- Titanium Reconstruction Plate 3.5 mm, curved Combi Hole Locking Plate 3,5 Ti Recon Plate 90-150-1104 – 90-150-1122
- Titanium One Third Tubular Locking Plate 3,5mm 90-0700-002 – 90-0700-014
- Titanium Distal Humeral Locking Plate distal-medial 3,5mm 90-0590-403 – 90-0590-514
- Titanium Distal Humeral Locking Plate dorsolateral 3,5mm 90-0590-203 – 90-0590-314
- Titanium Distal Humeral Locking Plate medial 3,5mm 90-0590-107 – 90-0590-115
- Titanium Proximal Humeral Locking Plate 3,5mm 90-0580-003 – 90-0580-012
- Titanium Clavicle Hook Locking Plate 3,5mm 90-0800-154 – 90-0801-188
- Titanium SB Clavicle Locking Plate 3,5mm 90-142-1106 – 90-142-1210
- Titanium SB Clavicle Locking Plate 3,5mm 90-144-1103 – 90-144-1208
- Titanium Olecranon Locking Plate medial 3,5mm 90-0590-602 – 90-0590-712
- Titanium Proximal Tibia Locking Plate lateral 3,5mm 90-162-1104 – 90-162-1216
- Titanium Distal Tibia Locking Plate anterolateral 3,5mm 90-0612-005 – 90-0613-021
- Titanium Distal Tibia Locking Plate medial 3,5mm 90-0601-004 – 90-0600-014
- Titanium Metaphyseal Locking Plate straight 3,5mm 90-168-006 – 90-168-0020
- Titanium Distal Fibula Locking Plate 3,5mm 90-0610-003 – 90-0611-011
- Titanium Calcaneus Locking Plate 3,5mm 90-0560-008 – 90-0570-010
- Titanium Calcaneus Type ”B” Locking Plate 3,5mm 90-0571-015 – 90-0572-015

Screw:

- Titanium Locking Screw Fullthreaded Self-Tapping Ø 2,7mm Stardrive Bit 10, purple 90-0030-010ST – 90-0030-070ST
- Titanium Locking Screw Fullthreaded Self-Tapping Ø 2,7mmStardrive Bit 10 polyaxial, grey 90-0055-10PA – 90-0055-70PA
- Titanium Locking Screw Fullthreaded Self-Tapping Ø 3,5mm Stardrive Bit 10, blue 90-004-010ST – 90-0040-070ST
- Titanium Locking Screw Fullthreaded Self-Tapping Ø 3,5mm Stardrive Bit 10 polyaxial, grey 90-0045-10PA – 90-0045-70PA
- Titanium Locking Screw Fullthreaded Self-Tapping Ø 3,7mmStardrive Bit 10 polyaxial, grey 90-0035-10PA – 90-0035-70PA
- Titanium Cortical Screw Fullthreaded Self-Tapping Ø 3,5mmHexagonal Socket 90-0004-010ST – 90-0004-080ST
- Titanium Cancellous Screw Fullthreaded Ø 4,0mmHexagonal Socket 2,5mm 90-0007-010ST – 90-0007-060ST

Washers

- Titanium Locking Distance Bolt Ø 3,5mm Stardrive Bit 10 90-0060-010
- Titanium Washer for Ø 2,7 / 3,5mm 90-0060-011WT

9.7 Locking Largefragment

DHS/DCS Plates

- Titanium locking DHS plate standard 5,0 mm Low Contact with combi hole 18-100-3502 – 18-100-3516
- Titanium locking DCS supracondylar plate 5,0 mm Low contact with combi hole 18-100-9506 – 18-100-9522
- Titanium locking DHS lag screw 18-100-0050 – 18-100-0145
- Titanium locking DHS compression screw 86-0200-0036
- 6,5 mm Spongiosaschraube 18-174-0025 – 18-174-3100

Plates:

- Titanium narrow locking plate straight 5,0 mm Low contact with combi hole
  87-0101-098 – 87-0101-440
- Titanium broad locking plate straight 5,0 mm Low contact with combi hole
  87-0231-2006 87-0231-2024
- Titanium broad locking plate pre-bent 5,0 mm Low contact with combi hole
  87-0100-116 – 87-0100-440
- Titanium proximal lateral tibia locking plate 5,0 mm
  87-4252-1104 – 87-4252-1216
- Titanium proximal tibia locking T-plate 5,0 mm
  87-0104-004 – 87-0104-008
- Titanium proximal tibia locking plate posteromedial 5,0 mm
  87-0103-004 – 87-0102-010
- Titanium distal tibia locking plate lateral 5,0 mm
  87-0106-005 – 87-0105-012
- Titanium proximal tibia locking plate lateral 5,0 mm
  87-0108-005 – 87-0107-013
- Titanium distal femoral buttress locking plate 5,0 mm with Combi Hole
  87-0110-005 – 87-4240-0213
- Titanium distal femoral locking plate 5,0 mm with combi hole
  87-4242-0105 – 87-4242-0213
- Titanium metaphyseal locking plate straight 5,0 mm
  87-4270-008 – 87-4270-0020

Screw:

- Titanium locking screw full threaded self-tapping Ø 5,0 mm Hexagonal socket width 3,5mm, gold
  87-0285-0514 – 87-0285-0599
- Titanium locking screw full threaded self-tapping Ø 5,0 mm Hexagonal socket width 3,5mm, polyaxial, grey
  87-0055-14 – 87-0055-100
- Titanium cortical screw full threaded self-tapping Ø 4,5 mm Hexagonal socket width 3,5mm, gold
  85-0008-012ST – 85-0008-120ST
- Titanium distance bolt Ø 5,0 mm Hexagonal socket width 3,5mm, blue
  87-0060-010
- Titanium Fixation bolt Ø 5,0 mm for cerclage wire Hexagonal socket width 3,5mm, grey
  87-4288-0100
- Titanium washer Ø 13,0 mm
  90-0060-011WT

9.8 Tools and instruments

Please note the respective information on the compatible instruments in our catalogues or surgical techniques.

- titan-locking-polyaxial-small+large (Katalog)
- Digi-Med_Osteo_OS (catalogue)

⚠ Under no circumstances may the implants be combined with products, components and instruments from other manufacturers. Combinations with products from other manufacturers can have a negative impact on the result of the procedure and are not permitted, as the components used may not be coordinated. It is recommended to use only instruments and accessories from the company. to be used.Digimed MedizintechnikDigimed Medizintechnik

10 EXCLUSION OF REUSABILITY

Once implants have been inserted, they must not be reused under any circumstances. The products are intended for single use only. Failure to observe the restriction (single-use device) can have serious consequences for the patient

- Failure of the implant (e.g. fracture)
- Lack of healing

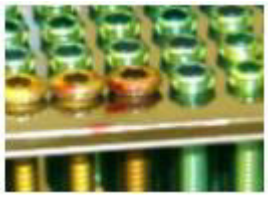
11 REPROCESSING

In principle, implants themselves may only be inserted once. Once an insert is complete, the implant must not be used again.

If implants are prepared for application and not used clinically, i.e. not implanted and not contaminated in the operating room with, for example, blood, tissue (contact with patients), they may generally continue to be used after reprocessing and sterilization. However, this does not apply,

- ✓ if the surface, e.g. color anodization (color coding) of the implants, has changed in such a way that a correct assignment to the corresponding instruments is no longer guaranteed.

All right



Not okay

After treatment of a patient infected with Creutzfeldt-Jakob disease, the accessories as well as the instruments for insertion / use must not be reused and must not be reprocessed. The products must be disposed of.

12 PREPARATION AND TRANSPORT

All system components are delivered non-sterile. It is therefore imperative that they be cleaned and sterilized before being used on the patient. In the case of reusable instruments, this applies to any reuse.

Transport of the implants / instruments in a closed container to the reprocessing site in order to avoid damage to the implants / instruments and contamination of the environment.

13 CLEANING & DISINFECTION

13.1 Basics

If possible, a mechanical process (RDG (washer-disinfector)) should be used for cleaning and disinfection. Due to the significantly lower effectiveness and reproducibility, a manual process – also using an ultrasonic bath – should only be used if a mechanical process is not available or in accordance with country-specific requirements (e.g. in Germany a mandatory mechanical process for critical B products). Pre-treatment must be carried out in both cases.

13.2 Pretreatment

The implants can be brushed under the surface of the water (tap water) until they are optically clean.

13.3 General information on machine cleaning/disinfection with a (RDG)

When choosing the RDG, it is important to pay attention to:

- that the RDG has been tested in principle (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- that, if possible, a tested program for thermal disinfection (A0 value > 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, risk of disinfectant residues on the products),
- that the program used is suitable for the products and contains sufficient rinsing cycles (at least three depleting steps after cleaning (or neutralization, if applied) or conductivity control recommended to effectively prevent detergent residues)),
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- that the air used for drying is filtered (oil-free, low in germs and particles) and
- that the RDG is regularly maintained, checked and calibrated.

When selecting the cleaning agent system used, care must be taken to:

- that it is basically suitable for the cleaning of invasive medical devices made of metals and plastics,
- that – if no thermal disinfection is used – a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the products

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as specifications for rinsing, must be strictly adhered to.

Expiration:

1. Insert the products into the RDG. Make sure that the products do not touch each other.
2. Launch the program.

3. Remove the products from the RDG after the end of the program.
4. Check and pack the products as soon as possible after removal.

13.4 Cleaning & disinfection

With regard to the responsibility for the professional cleaning and disinfection of the manufacturer's implants, the operator and product user are responsible. The country-specific guidelines must be observed. The aseptic regulations for the respective country-specific guidelines must also be observedDigimed Medizintechnik

The following instructions must be observed:

- The cleaning and disinfection medium used must be applicable for the cleaning/disinfection of implants made of high-alloy steel as well as titanium alloys and pure titanium, which is non-foaming, plasticizing (highly alkaline). Only approved cleaning and disinfection medium in accordance with (RKI, FDA, DGHM, DGSV, DGKH) may be used
- In order to be able to reprocess the implants optimally, the receptacle basket or the implants should be placed in such a way that the holes, threaded holes, clamping sliding holes can be rinsed completely and thoroughly.
- The manufacturer, reprocessing and sterilization validation is carried out individually packaged and not in trays!
- The instructions of the plant manufacturer with regard to mechanical processing must be observed.
- Loading of the receiving baskets or immersion pool screens of the preparation machine must be carried out in accordance with the manufacturer's instructions.
- Mechanical treatment may only be carried out with fully desalinated water (deionized water) in accordance with EN 285 Annex B
- Cold water specification corresponds to the drinking water supply (Drinking Water Ordinance of 20.12.2019)

Cleaning

Step	Parameter	
Pre-rinse with cold water	Rinsing temperature	18° to 21° C
	Exposure time	2 minutes C
Pre-rinse with cold water	Rinsing temperature	18° to 21°
	Exposure time	4 min
Clean	Cleaning temperature	55° to 58° C
	Exposure time	5 min
	Detergent	Neodisher®
	Concentration	0,50 %
Neutralization	Temperature	38° to 40° C
	Exposure time	3 minutes
	Medium	Neutralisatior
	Concentration	0,10 %
Intermediate flushing with intermediate emptying	Temperature	40° to 45° C
	Exposure time	2 x 2 min
	Medium	Deionized water
Rinse	Rinsing temperature	90° to 95° C
	Exposure time	5 min
	Medium	Deionized water

Disinfection

Step	Parameter	
Thermal disinfection	Disinfection temperature	90° C (Ao 3000)*
	Exposure time	300 s
Dry	Drying temperature	80° to 85° C*
	Drying	20 to 30 min

*Disinfection (worst-case validation carried out at 55°C with a holding time of 5 minutes)
*Drying (worst-case validation performed at 60°C for 30-35 minutes)

14 FUNCTIONAL TESTING AND PACKAGING

The products must be tested for cleanliness and functionality after reprocessing and before sterilization. If necessary, the remanufacturing process must be repeated until the product is visually clean.
Sort the cleaned and disinfected implants individually and pack them in single-use sterilization packages (single packaging) that meet the following requirements:

- ✓ DIN EN ISO/ANSI AAMI ISO 11607 (für USA: FDA-Clearance)
- ✓ suitable for steam sterilization (temperature resistance up to at least 137 °C (280 °F), sufficient vapor permeability)
- ✓ Adequate protection of the products or sterilization packaging against mechanical damage
- ✓ Regular maintenance according to the manufacturer's specifications (sterilization container)
- ✓ A maximum weight of 10 kg per package/contents of the sterilization container must not be exceeded

15 STERILIZATION

Only the following sterilization methods shall be used for sterilization; other sterilization methods are not permitted.

15.1 Steam sterilization:

The recommended sterilization method is "steam sterilization with saturated steam with fractionated vacuum" in accordance with EN ISO 13060 and DIN EN ISO 17665-1 and taking into account country-specific requirements.

- There must be 3 pre-vacuum phases with a pressure of at least 65 millibars,
- A sterilization temperature of at least 134°C (maximum 138°C).
- Holder time of at least 5 minutes (max. 10 minutes)
- The drying time must be at least 10 minutes (maximum 15 minutes)

16 STORAGE

Storage of the implants in a dry, clean and dust-free environment. No indication of durability or functional restriction is given for implants delivered non-sterile after manufacture, if they are stored properly.

17 REPAIRS & SERVICE

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this. If you have any complaints, complaints or information regarding our products, please contact us.

18 HANDLING

The system components must be carefully handled and stored. Damage or scratches on the implant can significantly impair the strength and fatigue resistance of the product.

19 DISPOSAL

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws. Specific instructions for this are not given by the manufacturer.

20 DISCLAIMERS & WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. However, we cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. We cannot accept any liability for any incidental or consequential damages.
Any product liability expires,

- in case of damage due to improper storage, handling, cleaning and / or sterilization
- in case of incorrect cleaning and sterilization
- in case of non-observance of these instructions for use

THE COMPANY ASSUMES NO LIABILITY IF IT CAN BE PROVEN THAT THESE INSTRUCTIONS FOR USE HAVE BEEN VIOLATED.Digimed Medizintechnik

21 INFORMATION

21.1 Batch traceability

In order to ensure the traceability of implants, EN ISO 13485 requires batch traceability from all parties involved in distribution:
Chapter 7.5.3.2. Specific requirements for active implantable medical devices and implantable medical devices
When establishing records for traceability, the organization must include all components and materials used, as well as working environment conditions, if these could cause the medical device to fail to meet its specified requirements.
The organization shall require that its agents or sales representatives keep records of the shipment of medical devices with a view to traceability and that such records be available for inspection.
Records must be kept of the name and address of the recipient of the shipping packaging.

Due to the small diameter of the implants, there is no direct marking on the product. For the purpose of traceability, the user must ensure that the product label is stored in the patient file.

21.2 LINK to the Summary on Safety and Clinical Performance Article 32

At the time of writing these instructions, the EUDAMED database was not yet active. Therefore, no link to the safety and clinical performance brief can be included here. The Summary on Safety and Clinical Performance is up-to-date and will be kept up to date. Digimed Medizintechnik

21.3 Serious incidents

Serious incidents involving the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established. This notification must be made immediately after the occurrence so that important reporting deadlines can be met, if necessary.
The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.
Upon receipt of your report, we will inform you of the further necessary measures within a reasonable period of time.

21.4 Implantation card Article 18 of MDR 2017/745

According to the definition of Article 18 paragraph (3), the devices are exempt from the obligation to have an implantation card. Nevertheless, we recommend that the labeling of the products be kept in the patient's file.

22 SYMBOL EXPLANATIONS

The CE marking with the identification number of the notified body applies exclusively to the implantable devices.

	Manufacturer		Observe the instructions for use
	Non-sterile		CE marking with number of the notified body
	Do not reuse		Batch designation
	Attention		Order number
	Medical		Only for professionals USA