ANTON HIPP
Instruments & Implants

Implants for Osteosynthesis

Instruction for Use

ENGLISH

IMPORTANT PRODUCTINFORMATION!

PLEASE READ CAREFULLY BEFORE EACH CLINICAL APPLICATION!

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Dear customer!
With your purchase, you will receive a high-quality product, the proper use of which is described in the following. In order to minimize hazards for patients and users, we ask you tu carefully read an oberve the instruction für use.
Anton Hipp GmbH also offers user training for our systems and products. Please contact your direct distributor or contact us.

The scope of these instructions for use refers to the following products or systems:

ARCOS® CMF System
Micro 1.2 System
TIN 1.6 System
MINI System 2.0
FRAKTUR System 2.3
REKONSTRUCTION System 2.7

ARCOS® Hand System
1.2 XS System
1.6 S System
2.3 M/L System
2.7 X/L System

ARCOS® Foot System
M/L 2.3 System
XL 2.7 System

DESCRIPTION
The ARCOS® Systems of Anton Hipp GmbH are plate and screw systems for craniomaxillofaciale osteosynthesis, hand- und foot osteosynthesis. The individual implants - systems differ based on the diameter of the respective titanium screws by the description and a color coding individually assigned to each implant - system.

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Basis UDI-DI
Plates 4066591PG01-01BL | Screws 4066591PG01-02BN

MATERIALS
Titan Grade 1 | ASTM F67 | ISO 5832-2
Titan Grade 2 | ASTM F67 | ISO 5832-2
Titan Grade 4 | ASTM F67 | ISO 5832-2
Titan Grade 5 - ELI | ASTM F136 |ISO 5832-3
TITAN Grade Nb ASTM F 1295 | ISO 5832-11
Screwbox (ULTRAFORM® N2320 003 PRO UNCOLORED)

MRT-Information

MR conditional
Titan-Implants are MR-suitable but not unrestrictedly safe.

Conditions that define the MR environment are static magnetic field strength, radiofrequency fields, specific absorption rate and artifact distortion around the image. In terms of artifact formation, the geometry of the implant is a contributing factor in addition to the material. Therefore, it may be necessary to optimize the MRI parameters accordingly.

INTENDED USE
The osteosynthesis implants of the ARCOS® systems are used for stabilization of bone segments or fragments, as well as bone malformations up to bony consolidation in craniomaxillofacial surgery and hand and foot surgery. Bone plates, screws and meshes are intended for single use only.

INDICATION/PURPOSE
(system-related)

ARCOS® CMF System

MICRO 1.2 System
Used in the upper cranial region and in the jaw area in areas that are not, or lightly, stressed.
- **Trauma**

Skull fractures | Orbital rim fractures | Frontal sinus fractures | Naso-orbital-ethmoidal fractures
- **Reconstruction of bone defects and malformations**

Skull cap | Orbita / zygomatic bone area | Dento-alveolar area | Dental processes of the jaws | Fixation of bone grafts (bone augmentation, alveolar ridge)

TIN 1.6 System
Is used in the middle and upper cranial region in areas that are not or lighlty loaded.
- **Trauma**

Le Fort I, II, III fractures | Zygomatic fractures | Orbital fractures | Frontal sinus fractures | Naso-orbital-ethmoidal fractures | Skull fractures
- **Reconstruction of bone defects and - malformations**

Le Fort I, II, III Level and for repositioning osteotomies in these levels | Maxilla | Orbita / Zygomatic region | Skull cap | Fixation of bone grafts (bone augmentation alveolar ridge)

MINI System 2.0
Is used in the upper jaw (maxilla) as well as in the lower jaw (mandible) in lightly loaded areas.
- **Trauma**

Craniofacial fractures and midface fractures | Mandibular fractures with various locations as median, paramedian fractures, mandibular body and mandibular angle fractures and in various forms as simple, multiple, oblique, and comminuted fractures | Lag screw osteosynthesis for sigital clefting
- **Orthognathic surgery if the midface and mandible including sagital cleft and chin plastic surgery**
- **Reconstruction of bone defects and malformations**

Fixation of bone grafts (bone augmentation, alveolar ridge)

FRAKTUR System 2.3
Used exclusively in the mandible (mandibular) in lightly to moderately loaded areas.
- **Trauma**

Mandibular fractures with different localizations as median, paramedian, mandibular body and mandibular angle fractures and in different forms as simple, multiple, oblique and comminuted fractures | Lag screw osteosynthesis for sigital fissure
- **Orthognathic surgery of the midface and mandible including sagital cleft and chin plastic surgery**

RECONSTRUCTION System 2.7
Used exclusively in the mandibular region.
- **Primary indication:** reconstruction of the mandible in a single step, with the ARCOS® 2.7mm Reconstruction Plate restoring mandibular continuity.
- Bridging of the mandibular continuity defect with an ARCOS® 2.7 mm Reko-Plate and additional fixation of free non-vascularized or microvascular pedicled bone grafts in the same surgical step; i.e. reconstruction with autologous bone immediately after resection of the mandible e.g. in case of resection of a tumor of the jaw or oral cavity, osteomyelitis, drug associated osteonecrosis of the jaw or osteoradionecrosis.
- **Secondary reconstruction** of the mandible, where the jaw resection has taken place at an earlier stage, the plate is then used to restore the former position of the jaw stumps to each other and to fix a microvascular or free bone graft to bridge the defect in the long term as a biological replacement.
  Mandibular fractures especially mandibular fragment fractures, mandibular comminuted fractures, mandibular defect fractures as well as fractures in the atrophic mandible where the load has to be bridged in sections of the mandible.
- Lag screw osteosynthesis in case of sigital cleavage

ARCOS® Hand System

1.2 XS System
Used for fractures of the middle and distal phalanx.
- **Osteosynthesis (Traumatology)**
- **Reconstructive surgery**

1.6 S System
Used for middle phalanxx fractures.
- **Osteosynthesis (Traumatology)**
- **Reconstructive surgery**
- **Arthrodese**

2.3 M/L System | 2.7 X/L System
Used for fractures of the proximal phalanx and metacarpal (MC) bone
- **Osteosynthesis (Traumatology)**
- **Reconstructive surgery**
- **Arthrodese**

ARCOS® Foot System

2.3 M/L System | 2.7 X/L System
Used for phalanx, metatarsal and tarsal fractures.
- **Osteosynthesis (Traumatology)**
- **Reconstructive surgery**
- **Arthrodese**

CONTRAINDICATION
- Non-reducible and stabilizable fractures (except reconstruction plates).
- Fractures of a severely atrophic mandible (excluding reconstruction plates and plates of the Mandibular 2.3mm Systems).
- Patients with manifest infection.
- Patients with metal allergy and foreign body hypersensitivity.
- Patients without adequate compliance who are unwilling or unable to follow aftercare instructions due to their mental or neurological condition.
- Patients with impaired blood flow or insufficient bone quality or quantity.
- Patients with an unstable physical and/or mental health condition.
- Mandibular reconstructions with ARCOS® System 1.2/1.6/2.0 implants.
- Secondary reconstructions with ARCOS® 2.0 plates without bone grafts.

COMPLICATIONEN
In many cases, undesirable results are not due to the implant but to clinical circumstances.
- Implant loosening due to insufficient tightening of the screws.
- Massive bending and fracture of the implant
- Bone necrosis, osteoporosis, limited revascularization, bone resorption, an poor new bone formation can lead to loosening, bending , tearing, or fracture of the implant or premature loss of fixation in the bone, resulting in pseudarthrosis.
- Delayed, insufficient or absent osseous build-up of the fracture due to incorrect alignment can lead to fracture of the implant.
- Increased connective tissue reactions may occur around the fracture site due to unstable fragment fractures.
- Early or late infection of a deep or superficial nature.
- Nerve damage as a result of the surgical trauma.

GENERAL WARNINGS
- The correct choice of implants is of utmost importance. It is essential to select the appropriate type and size for the specific patient. Implant components, bone or components/bones may loosen, bend, crack or break if the largest possible components are not used or an unsuitable position is present. The implant must be implanted in the correct anatomical position according to generally accepted standards. If a product unsuitable for the intended use is used, premature clinical implant failure may occur. Failure to use the correct component to maintain adequate blood supply and rigid fixation may result in bending or fracture of the implant and/or bone.
- Care must be taken to ensure that the forces to be transmitted by the implants are kept low through appropriate choice of biomechanics.
- The screws to be implanted must not lie in the fracture line. The screw threads must be completely fixed in the bone and the screw must be of sufficient length.

WARNINGS BONE PLATES
- As a result of cold forming during bending of the plate, the hardness of titanium increases and its deformability (pliability) decreases. It is therefore essential to ensure that the desired shape of the implant is achieved with as few bending steps as possible. Excessive bending can lead to postoperative plate fracture. Plates that have been bent back and forth too much should be discarded.
- When bending, acute angles and small bending radii must be avoided at all costs due to the potential risk of postoperative plate fracture. Therefore, straight plates must not be formed to the angulus.
- Aggressive use of bending instruments can lead to visible macroscopic damage to the implant (indentations, oval screw holes, etc.). In this case, the implant must be replaced with a new implant.
- Deformed screw holes not only mean an increased risk of breakage in these areas, but also affect the precise fit of the screw head in the plate.
- Tension-cut bone plate segments may need to be deburred prior to implant placement to avoid soft tissue injury or irritation.
- The plates should be shaped as closely as possible to the anatomical contour of the bone. Gaps between plate and bone should be avoided.
- Cutting the bone plate, may increase the risk of implant failure. When the surgeon cuts a plate, care must be taken to ensure adequate strength, support and fixation for the intended use. Cutting a plate between screw holes is the preferred method to maintain strength properties. Sharp edges should be ground to avoid soft tissue damage or irritation.
- In general, all plates with the corresponding color-coded screws from the same system must be used.
- All plates are to be implanted with the pre-sunk screw holes facing upwards.

WARNINGS BONE SCREWS
- Unless otherwise indicated, the bone screws are self-tapping, so that no thread needs to be pre-cut before inserting the bone screws. Exceptions exist in the case of compact cancellous bone and in the vicinity of a bone gap. In these cases, the thread should be pre-cut before inserting the screws.
- All screws may only be used with the correspondingly color-coded blades of the screws used.
- Before inserting the self-tapping screws, pre-drill with suitable and sufficiently large drills and determine the exact drilling depth for selecting the screw length. The drills and screws must be used with identical color coding.
- Self-drilling screws are not recommended for very small and thin bone parts because they can be displaced by the axial pressure during insertion.
- The screwdriver must be inserted into the screw head with slight axial pressure to ensure that the blade is fully seated in the screw head.
  This ensures correct axial alignment and complete contact between the screwdriver and the screw, thereby preventing damage to the screw head. Otherwise there is an increased risk of mechanical damage to the implant or the screwdriver blade.
- When inserting the bone screws, the screwdriver must be passed over the screw head with sufficient axial pressure to ensure that axial alignment and good contact between screwdriver and screw is achieved. Otherwise there is an increased risk of damage to the implant or screwdriver due to mechanical effects.
- Do not overtighten the screws when inserting them. Over-tightening can damage the screw head, cause the screw thread to tear out, break the screw and cause the screw to lose its tight fit. In the event of the screw thread being torn out, the appropriate emergency screws must be used.
- After completion of implantation, all bone screws must be retightened to ensure a firm connection between plate and screw.
- Before explanting an implant, the screw head must be cleaned with a scalpel or other suitable instrument so that the blade of the screwdriver is optimally seated in the screw head.

POSSIBLE SIDE EFFECTS
In many cases, complications are caused by the surgical procedure rather than the implant.
- Mucosal or tissue reaction
- Skin rash
- Loosening of the implant due to insufficient, improper attachment
- Possible nerve or blood vessel damage as a result of the surgical procedure.
- Increased connective tissue reaction in the fracture area due to unstable comminuted fractures.

The following side effects may occur after implantation:
- Pain, numbness, or hypersensitivity at the implant site
- Nerve irritation, nerve palsy, neuropathy, or hearing loss
- Occlusion disorder, restriction in opening the mouth, crossbite situation, disarticulation and/or trismus
- Dehiscence
- continuous bone resorption (stress shielding)
- Protrusion
- Infection
- Material incompatibility
- Bone necrosis, osteoporosis, limited revascularization, bone resorption, and poor new bone formation can lead to loosening, bending, tearing, or fracture of the implant or premature loss of fixation in the bone, resulting in pseudarthrosis.

ACCESSORIES / COMBINATION PRODUCTS

Instruments
Plate cutting instruments are used to divide or shorten bone plates in the area of the bars.

When cutting, make sure that the cut parts do not fling away, therefore do not point them at people when cutting and possibly cover them during the cutting process.
The plate part to be used must be deburred after cutting to avoid frictional conditions on the fabric..
Drills / drilling aids should always be selected in the shortest version to ensure the best possible concentricity. It should be checked whether the drill connection and drill aid are compatible.
Basically, work with speeds of <= 1000 rpm.

When drilling, ensure sufficient cooling with an NaCl solution to minimize the heat load on the bone. This is the only way to minimize the risk of bone demineralization.
Depth gauges are used to measure the screw length with the implant plate. The value displayed on the depth gauge corresponds to the screw length as indicated on the packaging.

The implants of Anton Hipp GmbH must never be combined with products, components and instruments (with the exception of the instruments mentioned) of other manufacturers. Combinations with products from other manufacturers can have a negative influence on the result of the procedure and are not permitted, as the components used may not be compatible with each other.

APPLICATION AND SAFETY INSTRUCTIONS

The products must be checked for defects, cracks, nicks 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 first use.

SAFETY PRECAUTIONS

ARCOS® CMF System

We would like to point out that implants only fulfill their function correctly if the following basic rules are observed:
1. Implants serve only to promote healing and are not a substitute for intact tissue and bone material.
2. Apart from mandibular bridging plates and arthrodesis restorations, implants are designed to perform their function only until bone healing (usually 6-10 weeks). Delayed healing, impaired bone healing, subsequent bone resorption, or even injury can place excessive stress on the implant, resulting in loosening, bending cracking, or fracture. Postoperatively, the patient must be on a passaged diet.

3. The surgeon should discuss in detail with the patient the surgical result to be expected when using this product. Special attention should be paid to postoperative aspects, such as proper postoperative nutrition with a passed diet and the need for regular medical aftercare.
4. The patient must be instructed to notify the surgeon immediately of any unusual change in the surgical site. If a change is noted at the fixation site, the patient must be closely monitored. The surgeon should consider the possibility of clinical implant failure and discuss with the patient the necessary measures to promote healing.
5. All implants must be inspected before each clinical use.
6. Bending templates must not be implanted under any circumstances.
7. The reuse of explanted as well as already formed implants is not permitted. An undamaged-looking implant may show signs of fatigue due to previous unknown loads, which may lead to premature failure of the implant.
It may look undamaged on the outside, but previous stresses may have caused defects that can shorten the life of the product.
Implants that have already had contact with a patient or have been contaminated with blood/tissue must not be reused under any circumstances.
Failure to observe these precautions can have serious consequences.

ARCOS® Hand & Foot System

We would like to point out that implants only fulfill their function correctly if the following basic rules are observed:
1. Implants are used only to promote healing and are not a substitute for intact tissue and bone material.
2. When selecting implants, care must be taken to select them according to the patient's weight and activity level, as well as the fracture to be treated.
3. Care must be taken to ensure that the forces to be transmitted by the implants are kept low by a suitable choice of biomechanics.
4. Severe deformation of the implants must be avoided. However, correct bending of the plates does not cause damage.
5. Multiple deformations are to be avoided.
6. The reuse of implants is not allowed.
7. We strongly advise you to inform the patient about the advantages and disadvantages of implants.
8. Excessive loading of the patient's body weight should be avoided due to the limited strength of the implants. The implant may bend, fracture, or pull out of the bone in patients subjected to repetitive stress, suffering from delayed healing or delayed growth of the bone.
9. Before inserting the screws, the drill must be pre-drilled with suitable and sufficiently large drills and the exact drilling depth determined for the selection of the screw length.
10. Self-drilling screws are not recommended for very small and thin bone parts, as they can be displaced by axial pressure during insertion.

Failure to observe these precautions can have serious consequences.

CLEANING / DISINFECTION
Basics
If possible, a mechanical process (washer-disinfector) should be used for cleaning and disinfection. 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 mechanical process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility.
Pretreatment must be carried out in both cases.

Pretreatment
Implants

⚠ **Pretreatment of the implants is not required, as bone screws, bone plates and meshes that have already been in contact with a patient or have been contaminated must not be reused under any circumstances.**

Instruments
The following applies to the instruments for insertion and explantation:
Immediately after application (within a maximum of 2 h), coarse impurities must be removed from the products.
If, due to the duration of the application or as a result of organizational aspects, this time cannot be observed, the user must define and validate measures on his own responsibility in order to prevent the soiling from drying through:

1. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F).
2. Place the products in a sufficiently large pre-cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified exposure time so that the products are completely covered. Make sure that the products do not touch each other. Support the pre-cleaning by completely brushing all internal and external surfaces.
3. Activate the ultrasound for a renewed minimum exposure time (but not less than 5 min).
4. Remove the products from the pre-cleaning bath and rinse them thoroughly with water at least three times (at least 1 min).

When selecting the cleaning agent to be used, it is important to ensure that,
- that this is basically suitable for cleaning invasive medical devices made of metals and plastics,
- that the cleaning agent is suitable for ultrasonic cleaning (no foam development),
- that the detergent is compatible with the products.

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or disinfectant, as well as specifications for post-rinsing, must be strictly adhered to. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only a soft, clean and lint-free cloth for drying (Caution: Be careful with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can stick!) and/or filtered air.

Mechanical cleaning/disinfection (WD)
When selecting the WD, it is important to ensure that,
- that the WD basically has a tested effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking according to 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 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 WD is regularly maintained, checked and calibrated.

When selecting the cleaning agent system to be used, the following points must be observed
- that this is basically suitable for cleaning invasive medical devices made of metals and plastics,
- that, if thermal disinfection is not 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, the disinfectant, as well as the specifications for post-rinsing, must be strictly observed.
Procedure:
1. Place the products in the washer-disinfector. Make sure that the products do not touch each other.
2. Start the program.
3. Remove the products from the WD at the end of the program.
4. Check and pack the products as soon as possible after removal.

Proof of the basic suitability of the products for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognized (§ 19 MPDG) test laboratory using the pre-cleaning and cleaning agent Cidezyme / Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

FUNCTIONAL TESTING AND PACKAGING
The products must be checked for cleanliness and functionality after reprocessing and before sterilization. If necessary, the reprocessing process must be repeated until the product is visually clean.

Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) that meet the following requirements (material/process):
- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA-Clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F) sufficient steam permeability)
- Sufficient 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/content of the sterilization container must not be exceeded

⚠ In principle, the implants themselves may only be inserted once. Once an insertion has been completed, the implants may not be used again. If the implants are not clinically used and are not contaminated in the operating room, the implants may be reprocessed again.
However, this does not apply:
If the color anodization of the implants has changed in such a way that a correct assignment to the corresponding drills, bone screws, bone plates is no longer guaranteed. The service life of the implants is therefore over and the products must be disposed of.

STERILIZATION
Only the sterilization methods listed below may be used for sterilization; other sterilization methods are not permitted.

Steam sterilization
- fractionated vacuum process (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA-Clearance)
- validated according to DIN EN ISO 17665 (valid IQ/OQ (picking) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)

Sterilization time (exposure time at the sterilization temperature):
Germany
minimum. 5 minutes at 134 °C (273 °F)
USA
minimum 4 minutes at 132 °C (270 °F), Trocknungszeit minimum 20 minutes
France
minimum 5 minutes at 134 °C (273 °F) f required for prion inactivation Sterilization time 18 minimum
Other countries
minimum 5 minutes at 132 °C (270 °F) / 134 °C (273 °F)

PRODUCT LIFE
The service life of the products is largely dependent on its sterility. The implants themselves are not sensitive to environmental conditions. Furthermore, a lifetime of the products in clinical use cannot be determined. The physician and the patient usually decide on the retention in the body and thus on the service life. At the beginning, the implant serves as a bridge connection until the reduced bone has recovered. Anton Hipp GmbH guarantees an unlimited retention period of product-specific records in order to fulfill our obligation as manufacturer and distributor. The products are intended and designed for long-term implantation. To date, we are not aware of any negative feedback from the market.

STORAGE INSTRUCTIONS
Implants must be stored before use in such an environment that maintains their packaging and purity. Dry atmosphere, no extreme temperatures, no exposure to sunlight, ionized radiation and contaminated particles. To avoid corrosion, pay special attention to the absence of chemicals in the immediate vicinity.

DISPOSAL
Disposal of Medical Devices Unless otherwise specified, devices must be disposed of as medical devices in accordance with facility procedures.

PATIENT BEHAVIOR
It must be pointed out to the patient that the safety and service life of the implant depend on his behavior and activity. It is therefore contraindicated any form of competitive sport in which the implants are affected.

INTERACTION WITH DRUGS
Interactions with drugs are not known.

DISCLAIMERS/WARRANTY
The products are made of high quality materials and are subjected to quality control before delivery. However, should any defects occur, please contact our service department. However, we cannot guarantee that the products are suitable for the respective operation. This must be determined by the user himself. We cannot accept any liability for accidental or resulting damage.
Any product liability expires,
- In case of damage due to improper storage, handling, cleaning and / or sterilization.
- in case of faulty cleaning and sterilization
- in case of non-observance of these instructions for use

SYMBOLIC


Manufacturer


Date of manufacture

Non-steril


Do not reuse

Batch designation

Catalog number

Serial number

MR conditional


Store dry


Protect from sunlight

Prescription


Attention


Observe instruction for use

CE marking with number of the Notified Body

Medical product