The Anton Hipp ARCOS osteosynthesis system is divided into a total of 5 systems. The division is based on the application as well as on the diameter of the screw thread. The ARCOS systems 1.2, 1.6, 2.0 and 2.3 are (CMF) plate and screw systems for stabilization and rigid fixation in craniomaxillofacial fractures, in postoperative orthodontic surgery, and for the fixation of bone graft and bone replacement materials in the reconstruction of jaw and facial bones after defects as a result of ablative tumor surgery or other bone pathologies of the jaw and facial region.

3.1 INDICATIONEN (divided by systems)

### 3.1.1 STANDARD PLATE SYSTEMS

**ARCOS MICRO System 1.2mm** is used in the upper cranial area and in the jaw area in non-stressed or slightly stressed areas.

- **Trauma**
  - Skull fractures
  - Orbitarand fractures
  - Frontal fractures (sinus frontal)
  - Naso-orbital-ethmoidal fractures
- **Reconstruction of bone defects and bone defects**
  - Skullcap
  - Orbital / zygomatic area
  - Dento-alaevolar area - Tooth extensions of the jaws
  - Fixation of bone graft

**ARCOS TIN System 1.6mm** is used in the middle as well as the upper cranial area in areas which are not or slightly stressed.

- **Trauma**
  - Le Fort I, II, III Fractures
  - Zygomatic fractures
  - Orbital fractures
  - Frontal fractures (sinus frontal)
  - Naso-orbital-ethmoidal fractures
  - Skull fractures
- **Reconstruction of bone defects and bone defects**
  - Le Fort I, II, III level and in the case of osteotomies in these levels
  - Maxillary maxilla
  - Orbital / zygomatic area
  - Skullcap

**ARCOS MINI System 2.0mm** is used in Maxilla as well as in the lower jaw in slightly stressed areas.

- **Trauma**
  - Craniofacial fractures and facial fractures
  - Mandibular fractures with different localizations as Mediane, paramediane fractures, mandibular and Fractures of the jaws and in various forms as simple, Multiple, oblique and debris fractures
- **Orthognathic surgery of the middle face and mandible**
  - Including sagittal cleavage and chin plastic

With the purchase of this implant, you receive a high-quality product whose proper handling and use are described in the following. In order to keep risks and unnecessary stress to the patient as low as possible, we ask you to carefully read and keep the instructions for use.

### 1 Product description / identification

The range of Anton Hipp GmbH - ARCOS systems 1.2, 1.6, 2.0 and 2.3 are cranio-maxillofacial (CMF) plate and screw systems. The individual implant systems differ based on the diameter of the respective titanium screws by the description and a color code assigned to each implant system. Anton Hipp implants are manufactured from commercially pure titanium and titanium alloy according to DIN EN ISO 5832 (ASTM F 67-83 / ASTM F 136) standards.

The implants are intended to support normal bone healing during osteotomies, fractures and reconstructions, but not to replace normal body structures.

The surface of the implants is chemically passive, the material is antimagnetic. The implants are delivered "UNSTERILE". The corresponding instruments are made of different stainless steels according to DIN EN ISO 5832 (ASTM F 67-83 / ASTM F 136) standards.

### 2 Tests

The implants must be tested for their proper functioning before each use. Examine the implants for discoloration, cracks, scratches and other damage caused by improper storage and sterilization before use. Do not use damaged implants. Implants with surface or shape deviations must be sorted out.

### 3 Intended Purpose

The Anton Hipp ARCOS osteosynthesis system is divided into a total of 5 systems. The division is based on the application as well as on the diameter of the screw thread. The ARCOS systems 1.2, 1.6, 2.0 and 2.3 are (CMF) plate and screw systems for stabilization and rigid fixation in craniomaxillofacial fractures, in postoperative orthodontic surgery, and for the fixation of bone graft and bone replacement materials in the reconstruction of jaw and facial bones after defects as a result of ablative tumor surgery or other bone pathologies of the jaw and facial region.

*Image of instructions for use*
ARCOS FRACTURE System 2.3mm is used exclusively in the lower mandible (mandibular) in areas with light to moderate stress.

- Trauma
  - mandibular fractures with different localizations as Mediane, paramediane fractures, mandibular and Fractures of the jaws and in various forms as simple, Multiple, oblique and debris fractures
- orthognathic surgery of the mandible including sagittal Cleavage and chin plastic

MESH ARCOS Systems 1.2 / 1.6 and 2.0 System is used exclusively in the upper cranial and jaw areas in areas which are not or slightly stressed

- Reconstruction of bone defects and bone defects
  - the cranium
  - Fixation of bone graft
  - in the orbita, orbita floor and cheekbones
  - Fronto sinu
  - Dento-alveolar area - Tooth extensions of the jaws

IMF Screws (intermaxillary fixation), bone block screws, traction screws

IMF Screws (intermaxilläre Fixation)

- Temporary maxillomandibular fixation for indirect Stabilization of the upper jaw
  And mandible
- short-term fracture restoration
- Le Fort I Fractures
- Fractures in the toothless jaw
- lower jaw fractures

Bone Block Screws ARCOS 1.2 / 1.6 /2.0 Systems

- All screws of the above systems with larger Lengths are used for:
  - Fixation of bone blocks and transplants in the dentistry
  - fixation of small bone segments in case of fractures of all kind

Traction Screws ARCOS 2.0/2.3/2.7 Systems

- All screws of the above systems with larger ones Lengths are used as a pull screw for:
  - Fixation with sagittal cleavage

3.1.2 Special Plates Systems

Neuro-plates

ARCOS system MICRO 1.2 / TIN 1.6 / MINI 2.0mm are used exclusively in the upper cranial area for neurosurgery in areas which are not or slightly stressed

- Reconstruction of bone defects and malformations of the skullcap

Neuro sub-temporal Plates

ARCOS System TIN 1.6mm is used in the lateral, middle and upper cranial areas in non-stressed or slightly stressed areas

- Closure or bridging of skull defects
- Closing function of access to brain surgery, especially in the Temporal cranial region
- Reconstruction of bone defects and malformations of the skullcap

Borehole Cover

ARCOS system MICRO 1.2 / TIN 1.6 / MINI 2.0mm are used exclusively in the upper cranial area for neurosurgery in areas which are not or slightly stressed.

- Coverage of the borehole, e.g. by craniotom after entrances for neurosurgery in the cranial area
- Reconstruction of bone defects and malformations of the skullcap

Nasal Plates

ARCOS System TIN 1.6mm / MINI 2.0mm is used in the nose area in areas which are not or slightly stressed.

- Trauma
  - especially naso-orbito-ethmoidal fractures
- Reconstruction of bone defects and malformations of the nose e.g. in frontoethmoid meningoecephalozelae

Orbital plates

ARCOS System MICRO 1.2 / TIN 1.6mm / MINI 2.0mm is used in the orbit area in non-stressed or slightly stressed areas

- Trauma
  - zygomatic fractures
  - Orbitarand fractures
  - Orbita floor and wall fractures
- Reconstruction of bone defects and malformations
  - in the orbital region
  - Cheekbone
  - Orbital floor

Dysgnathia Plates

ARCOS System MICRO Mini 2.0mm, specially shaped plates for the treatment of jaw defects in the mandible (dysgnatia)

- Sagittal splitting (Sagittal split
  Osteotomy fixation)
- Displacement
  - mandibular forward displacement
  - mandibular backward displacement
  - mandibular swing

Le Fort I Plates

ARCOS System MICRO TIN 1.6 / Mini 2.0mm, specially designed plates for the treatment of jaw misalignment in the maxilla (dysgnathia)

- Upper jaw restoration
- Recovery alveolar process
  - fully developed alveolar process
  - vertically too high or short alveolar
- Displacement
  - Upper jaw advancement
  - mandibular backward displacement
  - Upper jaw displacement
  - Maxillary displacement of the maxilla
  - maxillary swing
Chin Plates
ARCOS System MINI 2.0mm, specially designed plates for the treatment of chin correction (chin plastics)
- correction of the anterior vertical height at:
  - Class II
  - Class III
- dento-alveolar compensation

• Displacement
  - sagittal augmentation
  - vertical reduction
  - sagittal reduction
  - Combination

Condyle Plates
ARCOS System MINI 2.0mm, specially shaped plates for the treatment of fractures of the temporomandibular joint
- Trauma
- Ankle joint extension
- Bad split with mandibular displacement

BSSO / mandibular compression plates
ARCOS System MINI 2.0mm, specially shaped plates for the treatment of fractures in the lower jaw body
- Compression of the fractures to each other by insertion
  - Corresponding forces by means of the compression holes in the plates

• Trauma
- mandibular fracture osteosynthesis
- Simple but also oblique fractures in the area
- mandibular median and paramedian
- mandibular body
- Lower jaw angle

Jaw angle plates system ARCOS 2.3mm is exclusively in the Lower-jaw angle range in areas with mild to moderate stress.
- Trauma
- Simple, multiple, oblique and debris fractures in the Mandibular angle
- Straight plates of ARCOS 2.3mm system are for supply
  - Of the atrophic lower jaw

Mandibular ARCOS RECONSTRUCTION System is 2.7mm
Exclusively in the mandibular area
- Primary indication: reconstruction of the lower jaw in one:
  - Single step, using the ARCOS 2.7mm reconstruction plate
  - Continuity of the mandible
- Bridging the lower jaw discontinuity defect with an ARCOS 2.7mm Reko plates and additional fixing of free not
  - Vascularized or microvascular
  - Bone graft in the same operative step; i.e.
    - Reconstruction with autologous bone immediately after resection
    - Of the mandible. In resection of a tumor of the jaw or
      - The oral cavity, osteomyelitis, medication
      - Jaw osteonecrosis or osteoradionecrosis
- Secondary reconstruction of the lower jaw
  - Dentistry has previously taken place
  - Plate then serves to restore the previous position of the jaw
  - Stumps to one another and to fix one
  - Microvascular or a free bone graft, the
  - Defect in the long term as a biological substitute
- Lower jaw fractures, especially mandibular
- Mandible fractures, mandibular fractures, and fractures
  - Atrophic lower jaw, in which, in sections of the mandible, the pressure must be bridged.

3.2 CONTRAINDICATION

• Non-reducible and stabilized fractures (except
  - Reconstruction plates).
• Fractures of a strongly atrophic mandible (except
  - Reconstruction plates and plates of the Mandibular 2.3mm
  - system).
• Patients with manifest infection.
• Patients with metal allergy and foreign body hypersensitivity.
• Patients without adequate compliance due to their mental or mental health
  - Neurological constitution are not willing or capable, which,
  - Follow-up instructions.
• Patients with restricted blood flow or poor bone quality or quality.
• Patients with unstable physical and / or mental health.
• Sub-jaw reconstruction with ARCOS implants of System 1.2 / 1.6 / 2.0.
• Secondary reconstruction with ARCOS 2.0 plates without bone graft.

3.3 Possible Side Effects

In many cases, unwanted results are not caused by the implant, but by clinical circumstances.
- Loosen the implant by unscrewing the screws.
- Massive bending and fracture of the implant
- Bone necrosis, osteoporosis, restricted revascularization, bone
  - resorption and poor bone regeneration can lead to loosening,
  - bending, tearing or fracture of the implant, or premature loss of
  - fixation in the bone, and thus to pseudoarthrosis.
- Delayed, insufficient or missing bony fracture due to incorrect
  - alignment can lead to fracture of the implant.
- There may be connective tissue reactions due to unstable
  - fragmentation fractures around the fracture site.
- Early or late infections of a deep or superficial type.
- Nerve damage due to the operation trauma.
- Titanium hypersensitivity reactions in patients after implants have been
  - rarely reported, and their importance must be further
  - investigated clinically.

4 Behavior of products in the magnetic field (artifacts)

The titanium implants are suitable (MR conditional), but not completely safe. Conditions defining the MR environment are static magnetic field
- strength, high frequency fields, specific absorption rate, and artifact
distortion around the image. In addition to the material, the geometry of
the implant also influences the formation of artifacts.

The titanium implants are MR-compatible up to a magnetic field strength
- of 1.5 Tesla (standard MRI devices). Despite the standard method with a
  magnetic field strength of 1.5 Tesla, exposure to the magnetic fields
- during MR tomography can occur.

Since each material (or any non-ferromagnetic material) is polarized in an
- external magnetic field, it exhibits a magnetic response to an external
- magnetic field. The smaller this polarization is, the lower the artefacts are
- in imaging in MRI devices.

Stronger magnetic fields or an enlargement of the image field can lead to
- significant positioning errors and artifacts. Depending on the MR pulse
- rate, the artefact size can vary significantly and possibly impair the
diagnostic significance of the MR imaging when the area in question is
- located in the immediate vicinity of the titanium implants (i.e., a few
  millimeters apart).

A safe application of higher magnetic field strengths (3 Tesla, 7 Tesla)
cannot be guaranteed, since these peculiarities can result in the
- interactions and potential hazards. For example, higher magnetic field
Implants are only used for the promotion of healing and do not represent a substitute for intact tissue and bone material. Apart from mandibular bridging plates and arthrodesis, the implants are designed to perform their function only until bone healing (usually 6-10 weeks). A delayed healing, disturbed bone healing, subsequent bone resorption or even an injury can lead to overloading the implant and thus lead to loosening, bending, cracking or fracture. Postoperatively the patient has to feed with the food.

The surgeon should discuss the operation result to be expected with the patient in detail when using this product. Particular attention must be paid to the postoperative aspects, such as the correct postoperative dietary diet and the need for regular medical follow-up.

• The patient must be instructed to notify the surgeon immediately of any abnormal changes in the operation site. If a change is detected at the fixation site, the patient must be closely monitored. The surgeon should consider the possibility of a clinical implant failure and discuss the necessary measures with the patient to help promote healing.

• All implants must be inspected before each clinical use.

• Bend templates may not be implanted under any circumstances.

• Re-use of implants as well as implants already formed is not permitted. An undamaged-looking implant may have fatigue phenomena due to previous unknown stresses which may lead to premature failure of the implant. Although it may look externally undamaged, defects can be caused by earlier loads which can shorten the life of the product. Implants that have already been in contact with a patient or have been contaminated with blood / tissue may under no circumstances be re-used.

Failure to observe these precautions can have serious consequences.

5.1 WARNINGS

• The right choice of implants is of utmost importance. The appropriate type and size must be chosen for the specific patient. Implant components, or bones, or components / bones may become loose, bend, crack, or break unless the largest possible components are used or an unsuitable position is present. The implant must be implanted at the correct anatomical position according to generally accepted standards. If a product that is unsuitable for the purpose of the application is used, premature clinical implant failure may occur. Failure to use the proper component to maintain adequate blood supply and rigid fixation may result in bend 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 by appropriate choice of biomechanics.

• The screws to be implanted must not be located in the fracture line. The screw threads must be completely fixed in the bone and the screw must have a sufficient length.

5.1.1 Bone Plates

• The hardness of titanium increases as a result of cold forming during bending of the plate and its deformability (bendability) decreases. It is therefore absolutely necessary to ensure that the desired shape of the implant is achieved with as little bending as possible. Excessive bending can lead to postoperative plate fracture. Plates that are too strongly bent back should be discarded.

• When bending, acute angles and small benders are to be avoided due to the potential danger of postoperative plate breakage. Therefore straight plates cannot be formed on the angle.

• An overly aggressive use of bending instruments can lead to recognizable macroscopic damage to the implant (impressions, oval screw holes, etc.). In this case, the implant must be replaced with a new, careful curved implant.

• Deformed screw holes not only mean increased risk of fracture in these areas, but also affect the exact seating of the screw head in the plate. Therefore the boards must be carefully bent.

• Tissue-cut bone segment segments may need to be deburred before implantation in order to avoid soft tissue injuries or irritations.

• The plates should be shaped as precisely as possible to the anatomical contour of the bone. Gaps between plate and bone should be avoided.

• Cutting the bone plate can increase the risk of a failure of the implant. When the surgeon cuts a plate, care must be taken to ensure sufficient strength, support and fixation for the intended use. Cutting a plate between the screw holes is the preferred method to maintain strength properties. Sharp edges should be ground to avoid soft tissue damage or irritation.

• Generally, all plates with the corresponding color-coded screws from the same system must be used. All plates must be implanted with the countersunk screw holes.

5.1.2 Bone Screws

• Unless stated otherwise, the bone screws are self-cutting, so that no threading needs to be done prior to insertion of the bone screws. Exceptions include: With compact spongiosa and near a bone gap. Here the thread should be pre-cut before the screws are inserted.

• All screws may only be used with the appropriate color-coded blades of the screws used, that is, Blue blade with blue screws (1.2 system), green blades with green screws (1.6 system), yellow blades with yellow screws (2.0 system), red blade with red screws (2.3 system).

• Before installing the self-tapping screws, drill with suitable and sufficiently large drills and determine the exact drilling depth for the selection of the screw length. The drills should be selected according to the screws to be used with the same color marking of the screws and the length.

• 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 screwdriver and screw, thereby preventing the screw head from being damaged. 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 guided over the screw head with sufficient axial pressure to ensure axial alignment and good contact between screwdriver and screw; otherwise an increased damage risk arises due to mechanical effects for the implant or screwdriver.
- Do not overtighten the screws. Tightening tightly can damage the screw head, cause the screw to break and the screw to lose its tightness.
- Tightening the screw tightly may cause the screw thread to run out. If the screw thread runs out, the corresponding emergency screws of the corresponding system should be used.
- After the implant has been completed, all bone screws must be tightened to ensure a firm connection between plate and screw.
- Before explanting an implant, the screw head slot must be cleaned using a scalpel or other suitable instrument so that the blade of the screwdriver is optimally positioned in the screw head.

- **Warnings and precautions for the use of self-drilling screws:**
  - It is recommended to use shorter screws (≤ 4 mm) for familiar bones (eg skull bones) in order to avoid excessive axial forces and torques. If the screws are difficult to insert into the bone at the beginning, predrilling of a guide hole facilitates insertion, especially for screws with a length of more than 4 mm. The use of a constant axial (downward) force on the screwdriver handle and an exact orientation of the screwdriver on the screw are recommended when inserting the screw to ensure a constant contact between the blade and the screw head. When the screw is inserted, the underside of the screw head comes into contact with the lowering of the bone plate so that a marked increase in resistance can be felt. The insertion of a screw in dense bones requires a high axial force and torque. The increased resistance during final tightening may not be so noticeable here. Therefore, special care must be taken when tightening the screw in order to avoid the risk of mechanical damage to the screw, screwdriver or bone hole.
  - Self-drilling screws can bend or break when used in a bicortical application

### 5.2 Use of original products

The implants and instruments are developed and manufactured precisely to each other. The use of plates and screws of other manufacturers together with ANTON HIPP implants may result in unpredictable risks and / or contamination of the material. As well as an incorrect alignment of the implant and the instrument so that the patient, the user or third parties are endangered. Under no circumstances may resorbable products and titanium implants (resorbable plate with titanium screws) be used together.

### 6 Materials

The surface of these implants is chemically passive and non-magnetic.

<table>
<thead>
<tr>
<th>Material</th>
<th>Specification</th>
<th>Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure Titan</td>
<td>DIN EN ISO 5832-2 (ASTM F 67-83) Bone Plates Grad 1-4</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>Titanium Alloy</td>
<td>DIN EN ISO 5832-3 (ASTM F 136) Bone Screws</td>
<td></td>
</tr>
</tbody>
</table>

- It is important to ensure that only instruments from Anton Hipp GmbH are used according to the catalog for the respective system.
- Combinations with products from other materials and from other manufacturers can adversely affect the results of the operation and are not permitted.

### 7 Storage Instruction

Implants must be stored before use in an environment where their packaging and purity are maintained. Dry atmosphere, no extreme temperatures, no exposure to sunlight, ionized radiation and contaminated particles. To avoid corrosion, make sure that there are no chemicals in the immediate vicinity.

### 8 Sterilization and Cleaning

The implants are delivered "UNSTERIL," as well as free from dirt and production residues and must be unpacked, cleaned and sterilized before use. Avoid touching the implants with your hands. In the case of non-sterile implants, the sterilization procedures must be properly validated and routinely controlled. The sterility of the implants sterilized in this way is the responsibility of the operator. Implants that have already been in contact with a patient or have been contaminated with blood / tissue may under no circumstances be re-used. When using, please take note of a higher contamination of the equipped implant container. Clean / disinfect implants that have touched you. After cleaning, reseal them in the implant container and then sterilize the fully equipped implant container.

The instrumentation is delivered free from dirt and production residues and must be cleaned and stored in the appropriate instrument trays for sterilization before use. Instrument trays and implant containers are to be sterilized and stored in the appropriate sterilization container.

#### 8.1 Basics

For the cleaning and disinfecting of the implants a machine procedure (RGD (cleaning disinfector) / disinfecter) should be used. A manual method - also using an ultrasonic bath should be used only in case of unavailability of a machine process due to the significantly reduced efficiency.

#### 8.2 Preparation

Pretreatment is not required since implants that have already been in contact with a patient or have been contaminated should under no circumstances be re-used.

#### 8.3 Machine cleaning / disinfection (RDG)

When selecting the RDG, care must be taken that:
- the RDG in principle has a tested effectiveness (for example, DGHM approval or CE marking according to DIN EN ISO 15883) if possible, a tested program for thermal disinfection (at least 5 min at 90 °C or A0 value > 3000) is used. (Risk of disinfectant residues on the implants during chemical disinfection)
- the program used for the implants is suitable and contains sufficient rinsing cycles
- for the final rinse, only sterile or low germicidal (max. 10 germs / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (eg Aqua purification / Aqua purificata valde) is used
- The air used for drying is filtered
  - the RDG is regularly serviced, checked and / or validated.
- When selecting the detergent system used, make sure that:
  - this is basically suitable for the cleaning of the implants
  - if a thermal disinfection is used, a suitable disinfecting agent with tested effectiveness (for example, DGHM approval or CE marking) is additionally used and that this is compatible with the detergent used
  - the chemicals used are compatible with the implants (see capital material resistance)

The concentrations specified by the manufacturer of the cleaning and disinfecting agents must be complied with. The proof of the basic suitability of the implants for effective machine cleaning and disinfection was carried out by an independent accredited testing laboratory using the "RDG G 7835 CD" (thermal disinfection, Miele & Cie, GmbH & Co., Gütersloh) and neodisher® Mediclean forte "(Dr. Weigert GmbH & Co.KG, Hamburg)."
Steam sterilization:

- must be carefully observed.

Attention:

one titanium plate or mesh to ensure the sterility of the implants
- regularly maintained according to the manufacturer’s requirements
- organic, mineral and oxidizing acids

8.4 Packing

Sort the cleaned and disinfected implants into the implant containers
and pack them in single sterilization packages (single or double pack)
and / or sterilization containers that meet the following requirements:
- According to DIN EN ISO 11607-1
- Suitable for steam sterilization (temperature resistance up to at least
137 °C, sufficient vapor permeability)
- Adequate protection of the implants or sterilization packages from
mechanical damage
- regularly maintained according to the manufacturer’s requirements
(sterilization container).
For sterilization in the Arcos implant trays, we recommend storing only
one titanium plate or mesh to ensure the sterility of the implants

![Image]

Attention:
There are various sterilizers. The manufacturer’s instructions for use
must be carefully observed.

Steam sterilization:
- fractionated vacuum process / pre-vacuum process (at least 3 pre-
vacuum cycles)
- steam sterilizer according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO 17665-1 (valid picking and
product-specific performance evaluation)
- Recommended sterilization temperature 134 °C (273 °F) according
to DIN EN ISO 17665-1
- sterilization time (exposure time at the sterilization temperature) at
least 5 min at 134 °C (273 °F)
- Drying for at least 20 minutes.

Proof of the basic suitability of the products for effective steam
sterilization was provided by an independent accredited testing
laboratory using the steam sterilizer "3870 EHS, Tuttnauer Europe B.V
Breda" using the fractionated vacuum process. The above-described
method was taken into account.
The flash sterilization process is not permitted in principle. Also, do not
use hot air sterilization, radiation sterilization, formaldehyde or ethylene
oxide sterilization, or plasma sterilization.

8.5 Material Resistance

When selecting the cleaning and disinfecting agents, please make sure that
the following ingredients are not included:
- Organic, mineral and oxidizing acids
- Strong alkalies (pH> 11 not permissible), mild alkaline cleaners
recommended
- Organic solvents (alcohols, acetone …), petrol
- Halogenated hydrocarbons, chlorine, iodine
- ammonia

Never clean all implants, implant containers and sterilization containers
with metal brushes or steel wool.
All implants, implant containers and sterilization containers may only be
exposed to temperatures not higher than 137 °C (279 °F)!

8.6 Reusability

The implants may only be brought into contact with a patient once and
sterilized a maximum of 50 times. Repeated reprocessing according to the
instructions given in the instructions for use may result in color changes.
These are purely optical and do not represent any functional deficiency.

9 Interactions with Drugs

Interactions with drugs are not known

10 Patient behavior

The patient must be aware that the safety and life of the implant depends
on its behavior and activity. Therefore, any form of performance and
competition is contraindicated in which the implants are affected.

11 Warranty

The implants were made of high quality titanium and subjected to quality
control before delivery. Should any errors occur, contact our service
department.
However, we cannot guarantee whether the implants are suitable for the
particular procedure. The user must determine this himself.

12 Standards - References

When cleaning, disinfecting and sterilizing, the following sources
should be observed:
- AKI - Guideline “Instrument preparation done correctly”
- RKI - Recommendation: “Requirements for hygiene in the
processing of medical devices DIN EN 285 Steam-large sterilizers
- DIN EN13060 steam sterilizers DIN EN ISO 15883-1-3 Cleaning
disinfectors
- DIN EN 868 / DIN EN ISO 11607-1 Packaging for medical products
to be sterilized in the final packaging
- DIN EN 556-1 Sterilization of medical devices - Requirements for
final packaging
- DIN EN ISO 17664 Sterilization - Information of the manufacturer
- DIN EN ISO 17665-1 Sterilization process - moist heat
- DIN EN ISO 14937 Sterilization of health care products
- DIN EN ISO 11737-1 Sterilization of medical devices -
Microbiological procedure Part 1
- DIN EN ISO 11737-2 Sterilization of medical devices -
Microbiological procedure Part 2
- DIN 58946-7 Sterilization, steam sterilizers
(AKI = working group instrument preparation / RKI = Robert Koch
Institute)
- ASTM F2119 - Standard Test Method for Evaluation of MRI Image
Artifacts from Passive Implants
Frequency Induced Heating On or Near Passive Implants During
Magnetic Resonance Imaging
- ASTM F2052 - Standard Test Method for Measurement of
Magnetically Induced Displacement Force on Medical Devices in the
Magnetic Resonance Environment

13 Information’s

DIN EN ISO 13485 requires all parties involved in distribution to ensure
the traceability of implants:
7.5.3.2.2 Particular requirements for active implantable medical devices
and implantable medical devices

Dateiname mit Revisionsstand
Instruction of USE I
Erstellt / geändert am: 01.09.2009/19.05.17
Erstellt von: jw/gh
Seite 6 von 8
Anton Hipp GmbH
Annastr. 25/11
D-78567 Fridingen
When defining the traceability records, the organization must include all components and materials used, as well as work environment conditions that could lead to the medical device failing to meet its established requirements. The organization must require that its agents or sales representatives keep records of the delivery of medical devices with regard to traceability and that such records are available for inspection. Records must be kept of the name and address of the consignee of the shipping packaging.

THE COMPANY ANTON HIPP GMBH SHALL NOT BE LIABLE IF ANY PROVISION OF THESE INSTRUCTIONS FOR USE IS PROVIDED.
### SPECIAL PLATES

**Attachment 1**

<table>
<thead>
<tr>
<th>Art.-Nr.</th>
<th>Special Plates</th>
<th>To combind with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.087.04-10.087.10</td>
<td>TITAN MICRO ORBITAL PLATES</td>
<td>all TITAN Bone Screws from 1.2 mm System</td>
</tr>
<tr>
<td>10.100.13</td>
<td>TITAN BOREHOLE-COVER</td>
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<tr>
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<td>TITAN ORBITAL-PLATES</td>
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<tr>
<td>11.090.07-11.090.12</td>
<td>TITAN H-NASALPLATES</td>
<td></td>
</tr>
<tr>
<td>11.092.01-11.099.01</td>
<td>TITAN ORBITAL FLOORPLATES</td>
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