You receive with the purchase of this implant a high grade product whose appropriate handling and use will be shown below. To limit the risks and unnecessary burden to the minimum, we ask you to read the instruction for use carefully and to keep it.

The range of the Anton Hipp GmbH systems consists of different system components, which all comprehend indications for skeletal osteosynthesis. Every implant system distinguishes, based on the diameter of the individual titan screws, through the description and an individual color code attached on every implant system. Anton Hipp implants are manufactured of commercial clean titan according to ASTM F67-95. The implants are provided for the support of the normal cure of the bones in the cases of osteotomy, fractures and reconstructions. However they are not provided to replace the normal structures of the body or to carry the body weight in the case of an inadequate cure of the bones. The surface of the implants are chemical passive, the material is nonmagnetic. The implants are delivered unsterile. The corresponding instruments are manufactured of different rustless steels according to ISO 7153-1 and EN 10088-3 and sporadical also of Ti6Al4V alloys according to ISO5832-3/ASTM F136.

1 Examination
The implants have to be examinated of their correct operation before every use. Please inspect the implants before their use for discoloration, cracks, air valleys or other damages which were evoked by inadequate storage or sterilization. Do not implant damage implants. Implants with discrepancies of the surface or the form have to be sorted out.

2 Area of application
The attending doctor is responsible for the selection of the instruments for special applications or rather the operative use, the adequate training and information to others and the adequate experiences for the handling of the instruments. The literature standing at the doctor’s disposal, comprehend details concerning specific areas of applications

INDICATIONS
- Dentofacial surgery
  Traumatology, orthopaedic surgery and surgery of a craniofacial malformation in the upper jaw, midface and the calvarium of the cranium.
- ENT
  Traumatology of the nose skeleton
- Neurosurgery
  Osteosynthesis of the skullcap
- Accident and hand surgery
  Osteosynthesis of the hand, forearm as well as the bony foot.

2.1 CONTRAINDICATION
- States of health which exclude a sufficient support of the implants or which retard the cure process as e.g. reduced blood supply, insufficient quality or quantity of the bones, existing or previous, not completely healed up infection.
- States of mind, which make a participation in the rehabilitation routine impossible.

3 Preventive measures / Instructions
We indicate that implants can only execute their functions correctly when the following basic rules are observed:
- Implants conduct only to the acceleration of cure and are not a substitute for intact tissues and bones materials
- When choosing the implants it has strictly to be observed that they are chosen according to weight and the degree of the patient’s activity as well as the treating fracture of the bone
- It has to be regarded that the transmitted power of the implants are helt lowly by choosing the suitable biomechanics.
- Strong deformation of the implants has to be avoided. However it doesn’t come to damages when the forming is executed with caution and the corresponding care.
- Repeated forming has absolutely to be avoided.
- The re-use of implants is not allowed.
- We strongly recommend to inform the patient about the advantages and disadvantages of the implants.
- Exceeding burden through the patient’s body weight has to be avoided due to the limited strength of the implants. The implant can deform, break or torn out of the bone when the patient is exposed to several strains, when he suffers from retarded cure or from retarded adhesion of bones.
- Before implanting of the screws it has to be pre-drilled with suitable and sufficient big trephines to find out the exact drilling depth for the choice of the length of the screws.
- Self-drilling screws are not recommended for very small and thin parts of the bone, because they can be dislocated by the thrust when implanting.
- When implanting the bone screws the screwdriver has to be directed with sufficient thrust above the screw head. This allows an axial alignment and a good contact between screwdriver and the screw. Otherwise arise a heightened risk of damages due to mechanic impact for implants or screwdrivers.

The nonobservance of these precautions can lead to fatal consequences.

3.1 WARNING
- The right choice of the implants is of utmost importance. It is very important to choose the right size and the suitable type for the specific patient. Implant components or bones or components/bones can come loose, curve, exhibit splits or break when the biggest component is not used or when an unsuitable position exists.
- Through osteotomies implants are exposed to too high strains because the muscular strength doesn’t tighten at equilibrium. Then the chance of the fracture cure is very limited due to braking or bending implant components. Both further precautions and internal and external shorings are required to increase the fracture stability and to limit the internal strain of implants and bones to a minimum until a radiography can firm the adhesion of the bones. Further treatments as transplantations of bones or a medial substitution osteotomy can also be considered.
- An osteotomy exposes the bone plate to higher strains. To achieve the highest fixation the biggest plate length as possible should be chosen. The record length must be chosen in such a way that the biggest possible number of screws can be used. The period of time without weight strain or only a low weight strain has to be extended accordingly until a solid adhesion of bones happen.
- Please avoid that the threads of the implanted screws are located in the fracture line. The threads of the screws have totally to be fixed in the bone and the screw has to exhibit a sufficient length.
- The Re-use of explanted implants is not allowed. An implant which looks like undamaged can through previous unknown strains show signs of fatigue. This can lead to a premature failure of the implant. It is not allowed to re-use implants when they have already had contact with a patient of when they were dirtied with blood/tissue.

4 Materials
The surface of these implants is chemically passive and not magnetic.

<table>
<thead>
<tr>
<th>Pure titanium</th>
<th>DIN EN ISO 5832-2 and ASTM F67-83</th>
</tr>
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<tbody>
<tr>
<td>It has to be observed that only instruments from the company Anton Hipp according to the catalogue for the corresponding system is used.</td>
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<tr>
<td>Combinations with products which are out of other materials and other manufacturers can influence the result of the operation negatively and are not allowed.</td>
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</tbody>
</table>
5 Storage Instruktion

Implants have to be stored before their use in such surroundings in which their packaging and cleanliness remain obtained (no dry atmosphere, no extreme temperatures, no exposition with sunlight, ionised radiation and contaminated particles). To avoid corrosion, please observe particularly that there are no chemicals within splitting distance.

6 Sterilization und cleaning

The implants are delivered “UNSTERILE”, free of dirt and production residues and have to be unwrapped, to clean and to sterilize before use. Clean the implants only with distilled water. Please avoid absolutely the touching of the implants with the hands. The sterilization procedure of the unsterile delivered implants has to be validated according to the rules and checked routinely. The operator is responsible for the sterility of the implants.

It is in no way allowed to re-use the implants when they have already had contact with a patient of when they were dirtied with blood/tissue. Please already pay attention to the application, to avoid contamination of the equipped implant box. Clean/disinfect the implants which have been touched and sort them afterwards back in the implant box. Then sterilize the whole equipped implant box.

The instruments are delivered free of dirt and production residues and before usage they have to be cleaned and stored in the corresponding instrument trays. Instrument trays and implant boxes have to be sterilized in the corresponding sterilization container and have to be stored.

6.1 Basics

When it is possible the implants should be cleaned and disinfected by a mechanical procedure (cleaning and disinfection machine/disinfector). A manual procedure (also when using an ultrasonic bath) should due to the less effectiveness only be used in case of non-availability of a mechanical procedure.

6.2 Pre-treatment

A pre-treatment isn’t necessary as it is in no way allowed to re-use the implants which have already had contact with the patient or which have been contaminated.

6.3 Mechanical cleaning/ disinfection

When choosing the cleaning and disinfection machine, it has to be observed that:
- the machine shows fundamentally an examined effectiveness (e.g. DGHM or FDA permission or rather a CE-marking according to DIN EN ISO 15883)
- as far as possible an examined program for the thermal disinfection (5 minutes at least at 90°C or the A-figure >3000) is used (a chemical disinfection has the risk of disinfection residues on the implants)
- the inserted program is suitable for implants and that sufficient cleaning cycles are performed.
- for the post-purge only sterile or almost sterile (max. 10 germ/ml) as well as endotoxin poor (max. 0,25 endotoxin unit) water (e.g. Aqua purificata/Aqua purificata valde) is used.
- the air which is used for drying is filtered.
- the machine is maintained, checked and validated regularly.

When choosing the cleaning agent system it has to be observed that:
- it is suited for the cleaning of the implants
- if a termic disinfektion is not used an additional suitable disinfectant with an examined effectiveness is used and that it is compatible with the used cleaning agent
- the used chemicals are compatible with the implants (see chapter material constancy)

From the manufacturer of the cleaning agent and disinfektant given concentrations must be absolutely kept.

The proof of the general ability of the implants for an effective mechanical cleaning and disinfection was done by an independent accredited test laboratory by using the “RDG G 7346 CD” (thermic disinfection, Miele & Cie, GmbH & Co., Gutersloh) and the cleaning agent “Neodisher mediclean forte” (Dr. Weigert GmbH&Co.KG, Hamburg).

6.4 Packaging

Sort the cleaned disinfected implants in the implant boxes and package them in one-way sterilization packaging (single or double packaging) and/or sterilization container, which correspond to the following specifications:
- Suitable for the steam sterilization (temperature-resistance) until 137° (279°F) at least, enough permeability of steam
- Sufficient protection of the implants or rather sterilization packaging against mechanical damage
- Maintained according to the manufacturer information

When sterilizing the implant boxes we recommend to placing only two titan plates on top of each other to ensure the sterility of the implants.

6.5 Attention:

There are different kinds of sterilizer. The instruction for use of the manufacturer for the recommended use has to observed exactly.

Steam sterilization:
- Fractionated vacuum method/ preliminary vacuum method or gravitation method² (with sufficient drying of the product)
- Steam sterilizer according to DIN EN 13060 and DIN EN 285
- Validated according to DIN EN ISO/ANSI AAMI ISO 17665 (valid consignment and product-specific performance evaluation)
- Maximal sterilization temperature 134°C (273°F; plus tolerance according to DIN EN ISO/ANSI AAMI ISO 17665)
- Sterilization time (exposure time at sterilization temperature) 5 min at least³ at 132°C (273°F) / 134°C (273°F)

³ The use of the less effective gravitation method can only be effected when the fractionated vacuum method/ preliminary vacuum method is not available.

² or rather 18min (prions inactivations)

The evidence of the general use of the instruments for effective steam sterilization was provided by an independent accredited test laboratory by using the steam sterilizer “Systec V-150, Systec Labor- Systemtechnik, Wettenberg” by using the fractionized vacuum method or the gravitation method. In this connection the above-described method was considered.

The flash sterilization method is generally not allowed. In addition do neither use hot air sterilization, radiosterilization, formaldehyde or ethylene oxide sterilization nor plasma sterilization.

6.5 Material constancy

When choosing the cleaning agent and disinfektant please observe that the following constituent parts are not included:
- Organic, mineral and oxidated acids
- Intensive bases (pH>11 is not allowed), alkaluescent cleaners are recommended
- Organic solvents (Alcohols, Acetones,…), Benzines
- Halogenated carbon hydrides, chlorine, iodine
- ammonia
Do never clean the implants, implant boxes and sterilization containers with metal scrubber or steel wool.

All implants, implant boxes and sterilization containers can only be exposure to temperatures which do not exceed 137° C (279° F)/

6.6 Reusability
The implants can only once keep in touch with the patient and can 50 times at most be sterilized. If they are treated repeatedly according to the instructions for use they can get a change in color. These are purely optical and don’t mean a functional defect.

7 Interaction with pharmaceutical products
Interactions with pharmaceutical products are not known.

8 Patient’s behaviour
It has to point out to the patient that the reliability and the expectance of the implant are up to his behavior, his activity and his body weight. Therefore every kind of competitive and serious sports is contraindi-
cated when the implants are concerned.

9 Warranty
The implants are manufactured of high grade titan and before the deli-
very they are checked by the quality inspection. Should there neverthe-
less occur defects please contact our service. However, we cannot furnish a warranty if the implants are suitable for the individual surgery. The operator has to determine by himself.

10 Standards – References
When cleaning, disinfecting and sterilizing please take the follow-
ing references into consideration:
- AKI – guideline „Instrumenten-Aufbereitung richtig gemacht“
- RKI – recommendation: „Anforderungen an die Hygiene bei der
  Aufbereitung von Medizinprodukten DIN EN 285 steam large steril-
ization
- DIN EN13060 steam small sterilization DIN EN ISO 15883-1-3
  cleaning and disinfection devices
- DIN EN 868 / ANSI AAMI ISO 11607 Packaging for medical pro-
ducts which have to be sterilized in the final packaging
- DIN EN 556-1 Sterilization of medical products – Requirements of
  the final packaging
- DIN EN ISO 17664 Sterilization – Information from the manu-
facturer
- DIN EN ISO 17665-1 Sterilization method – humid heat
- DIN EN ISO 14937 Sterilization of products for the health care
- DIN EN ISO 11737-1 Sterilization of medical products – microbiolog-
ical method section 1
- DIN EN ISO 11737-2 Sterilization of medical products – microbiolog-
ical method section 2
- DIN 58946-7 Sterilization, steam sterilization
  (AKI=Arbeitskreis Instrumenten-Aufbereitung / RKI = Robert-Koch-
Institut)

11 Information
DIN EN ISO 13485: 2003 demands to the guarantee of the retraceability of implants of all parties involved in the distribution

7.5.3.2.2 Special requests for active implantable medical products and implantable medicine products
When defining the records for the retraceability the organization has to involve all used component parts and materials as well as the require-
ments of the working environment if they could lead to the case that the medical product does not comply with the setted requirements.

THE COMPANY ANTON HIPP GMBH ASSUMES NO LIABILITY IF THIS INSTRUCTION WAS DEMONSTRABLY INFRINGEMENT.