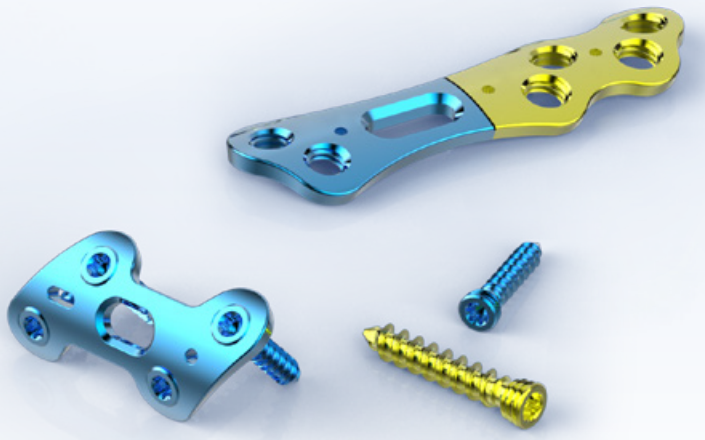
AGOMED

INSTRUCTION FOR USE

FOOT AND ANKLE IMPLANTS



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VERSION 03

AGOMED MEDIZIN-TECHNIK GMBH

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PRODUCTS

- Forefoot Plating Systems 2.7
- Rearfoot Plating Systems 3.5
- Foot Surgery System 3.5
- Agofix 4.0 and Anterior Plating System 4.0
- Mini Foot Plating System
- Cannulated standard screws
- Cannulated CBS Compression screws
- Cannulated interference screws
- A-TEC Lag- screws

IMPORTANT NOTES

Read these instructions for use carefully before use and keep them easily accessible for the user or operator.

You will find important instructions for use and other product-specific indications in the respective surgical descriptions!

Read the warnings marked with this symbol carefully. Improper use of the products can lead to serious injury to the patient, the user or third parties.

Implants are designed for single use and not for reuse. All components are supplied NON-STERILE. They must be subjected to an appropriate reprocessing process before initial use. All packaging materials must be removed before the reprocessing process.

FIELD OF APPLICATION

The implants may only be used by trained and qualified personnel. The products are intended exclusively for the use described below.

INTENDED PURPOSE

The AGOMED foot system is used on the foot for fractures, osteotomies and arthrodeses.

The AGOMED Cannulated Screws are used to treat fractures, osteotomies and arthrodesis.

INDICATIONS

- Fractures of the distal, middle and proximal phalanges and metacarpals.
- Fractures, osteotomies and arthrodesis of the small bones, especially the tarsals, metatarsals and phalanges.
- Fractures and osteotomies of the calcaneus.
- Fixation of fractures, osteotomies, malpositions and pseudarthrosis (“non-unions”) of the distal tibia and fibula.
- Fractures, osteotomies and pseudarthroses (“non-unions”) of the distal and proximal humerus are indicated.

CONTRAINDICATIONS

- Existing or suspected infections at or near the implant site.
- Known allergies and/or hypersensitivity to implant materials.
- Insufficient or poor bone substance to securely anchor the implant.
- Patients with insufficient ability and/or willingness to cooperate during the treatment phase.
- The combination of this implant with implants of other origin is contraindicated.

POSSIBLE ADVERSE EFFECTS OF THE IMPLANT SYSTEMS

In most cases, possible complications are clinical rather than implant/instruments related. These include, but are not limited to

- Loosening of the implant due to inadequate fixation.
- Metal hypersensitivity or allergic reactions.
- Bone necrosis, osteoporosis, insufficient revascularization, bone resorption and poor bone formation, which can lead to early fixation loss.
- Soft tissue irritation and/or nerve damage due to surgical trauma.
- Early or late infection, both superficial and deep.
- Increased fibrous tissue reaction around the surgical field.
- Complications during implant removal due to insufficiently freely prepared implant.

Taking into account the clinical condition and medical history of the patient, the treating physician must ensure that the use of AGOMED Hand Implants is appropriate for the individual case based on a patient-specific risk/benefit assessment.

SAFETY INSTRUCTIONS

The products are intended for single use and may not be reused.

The treating surgeon is responsible for the correct selection of patients, for the necessary training, the selection and insertion of implants based on sufficient experience and the decision to leave implants post-operatively or to remove them again.

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. Post-operatively, the patient has to eat a diet that has been passed.

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 post-operative aspects, such as the correct post-operative diet with a passive diet and the need for regular medical follow-up.

The choice of the correct product is extremely important. The product must be implanted at the correct anatomical position according to the generally accepted standards of Osteosynthesis. Using a product that is not suitable for the intended use may result in premature clinical implant failure. If the correct component is not used to maintain adequate blood supply and rigid fixation, the implant and/or bone may loosen, bend or break.

The product must be handled and stored with care. Damage or scratches to the implant can significantly reduce the strength and fatigue resistance of the product.

An implant that has already been inserted once must never be reused. Although it may look undamaged on the outside, previous exposure may have caused defects that can shorten the life of the product.

All implants must be inspected before each clinical use.

The patient must be instructed to inform the surgeon immediately of any unusual change in the surgical site. If a change in the fixation site is detected, the patient must be closely monitored. The surgeon should consider the possibility of clinical implant failure and discuss with the patient the necessary measures that may help promote healing.

Cold forming during bending of the plate increases the hardness of titanium and reduces its deformability (bendability). 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 should be avoided due to the potential risk of postoperative plate fracture. For this reason, straight plates should not be formed to the angulation.

Too aggressive use of bending instruments can lead to visible macroscopic damage to the implant (indentations, extended screw holes, etc.). In this case, the implant must be replaced by a new, carefully bent one.

Deformed screw holes not only mean an increased risk of fracture in these areas, but also impair the precise seating of the screw head in the plate. Therefore, the plates must be bent carefully.

Trimmed bone plate segments may need to be deburred before implantation 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.

Do not use plates in addition to the reconstruction plates to bridge bone defects in non-reducible, unstable comminuted fractures or for reconstruction. If they are used for this purpose nevertheless, this may result in premature implant failure.

The self-drilling screws are not recommended for very small and thin bone fragments, because the fragments can be displaced by the axial pressure when inserting the screws.

Unless otherwise indicated, the bone screws are self-tapping, so there is no need to cut a thread before inserting the bone screws. Exceptions are made in the following cases, among others:

- When bone screws are inserted near a bone gap. In these cases, the thread may need to be tapped.
- If the underside of the screw head comes into contact with the bone or with the screw head recess of the bone plate during insertion of the screw, a sudden increase in resistance can be clearly felt. The screw must be tightened carefully to avoid the risk of mechanical damage to the screw, screwdriver or bone hole. In the case of compact cancellous bone and near a bone gap, the thread should still be cut before inserting the screws.

In the case of traction screws, threads must be cut before inserting the screws into the drill holes. They are contraindicated for self-tapping use.

When inserting all locking screws, a drill guide must be used to ensure proper screw placement. Without using a drill guide, the screw may not lock into the plate.

When using locking screws, the first screw should be screwed into the plate, but not locked until the second screw is inserted and locked.

The screws should not be overtightened during insertion. Overtightening can damage the screw head, lead to screw breakage and loss of frictional tightness of the screw.

Overtightening the screw can cause the screw thread to tear out. If the screw thread is torn out, a replacement screw should be used.

After implantation is complete, all bone and/or locking screws must be retightened to ensure a firm connection between plate and screw.

The screwdriver must be inserted into the screw head with light 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 screw, thus preventing damage to the screw head. Otherwise, there is an increased risk of mechanical damage to the implant or the screwdriver blade.

Before explanting an implant, the screw head slot must be cleaned with a scalpel or other suitable instrument to ensure

that the blade of the screwdriver fits optimally in the screw head.

AGOMED implants are usually designed for temporary use and can be removed after sufficient bone healing. Implants are not intended as long-term replacements for intact bone material. The usual period of use of implants for mechanical support of Osteosynthesis is between 30 days and 6 months.

USE OF ORIGINAL PRODUCTS

The implants and instruments are developed and manufactured in a precisely coordinated manner. The use of products from other manufacturers together with AGOMED products may involve unforeseeable risks and/or contamination of the material and incorrect alignment of the implant and instrument so that the patient, the user or third parties are endangered.

MATERIAL SPECIFICATIONS

The AGOMED bone plates and bone screws can be made of commercially available pure titanium (CP) or titanium alloy. Both materials are biocompatible, corrosion-resistant and non-toxic in the biological environment and allow artefact-free imaging.

The Smart Fit screws are made of stainless steel 1.4441 according to ISO 5832-1.

STORAGE

The products must be protected from direct sunlight during storage.

The products must be kept dry.

PREPARATION

Implants that have been in contact with body fluids or have been contaminated during surgery must not be reused.

When selecting the cleaning agents, disinfectants and devices to be used, care must be taken at all stages to ensure that

- They are suitable for the intended use (e.g. cleaning, disinfection, ultrasonic cleaning).
- The detergents and disinfectants are aldehyde-free (otherwise fixation of blood stains).
- These have a tested effectiveness (e.g. VAH/DGHM or CE marking).
- The detergents and disinfectants for the products are suitable and compatible with the products.
- The manufacturer's instructions with regard to concentration, exposure time and temperature are observed.

In the case of the auxiliary cleaning agent, both in the pre-cleaning stage and in the cleaning process, care must be taken to ensure that:

- Only clean, lint-free cloths and/or soft brushes are used. The use of metal brushes or steel wool is prohibited.
- If necessary, aids such as cleaning pens, syringes, and cannulas, bottle brushes for cannulated products or products with lumen should be used.

Instrument and implant trays are intended for sterilization, transport and storage of products. They are not intended for cleaning and disinfection when loaded. The products must be removed from the trays and cleaned separately.

Automatic cleaning process:

Step	Time (min)	Process	Detergents	Temp. (°C)
1	2	Pre-cleaning	Tap water	cold
2		Draining		
3	5	Cleaning	Tap water; 0.5% alkaline cleaning (Mediclean fortet)	55
4		Draining		
5	3	Washing	PU Water	cold
6		Draining		
7	2	Washing	PU Water	cold
8		Draining		

Drying is device-specific and the drying temperature must not exceed 141 (°C).

AUTOMATIC DISINFECTION PROCESS

For thermal disinfection, the specifications of DIN EN ISO 15883 Part 1 are complied with. Thermal disinfection corresponds to the A0 concept (A0 value 3000). The thermal disinfection is to be carried out using the following parameters:

- Holding time:>5 minutes
- Temperature: 92°C±2°C
- With VE water.

MANUAL DISINFECTION

- Put the cleaned and controlled products into the disinfection bath for 15 minutes (e.g. CIDEX® OPA solution). The products must be sufficiently covered and individual components should not damage each other. The manufacturer's instructions regarding exposure time, temperature and concentration of the disinfectant used must be complied with
- Multiple back and forth movement of moving parts
- Large lumens must also be filled inside
- Cannulated products (products with cavities whose diameter is less than or equal to 1/6 of the length of the product), e.g. cannulated screws, must be filled with

disinfectant and flushed with a syringe and appropriate cannula (flushing volume 30 ml)

- Rinse with cold (T < 40°C) or warm (T > 40°C) water for at least one minute (lumens and cannulated products must also be rinsed from the inside using syringes and appropriate cannulas); water pressure guns can also be used
- Visual inspection of the products; if necessary, repeat the cleaning and disinfection process until there is no visible contamination
- The products must be completely dried immediately afterwards (compressed air drying is recommended)
- Check the products

Packing of the products as soon as possible, if necessary after additional post-drying.

CONTROL

After cleaning and disinfection, check all implants for damage, contamination, and check for damage (e.g. corrosion, damaged or discolored surfaces). Implants that are not in perfect condition must be sorted out and disposed of.

STERILIZATION

132°C / 270°F, at least 3 minutes, drying at least 20 minutes

Or

134°C / 273 °F, at least 5 min., A holding time of 18 minutes should not be exceeded, drying at least 20 min

EXPLANATION OF SYMBOLS

Item Number

Batch designation

Number


Follow the instructions for use


Not for reuse


Manufacturer


Date of manufacture


Store dry


Store away from direct sunlight

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main