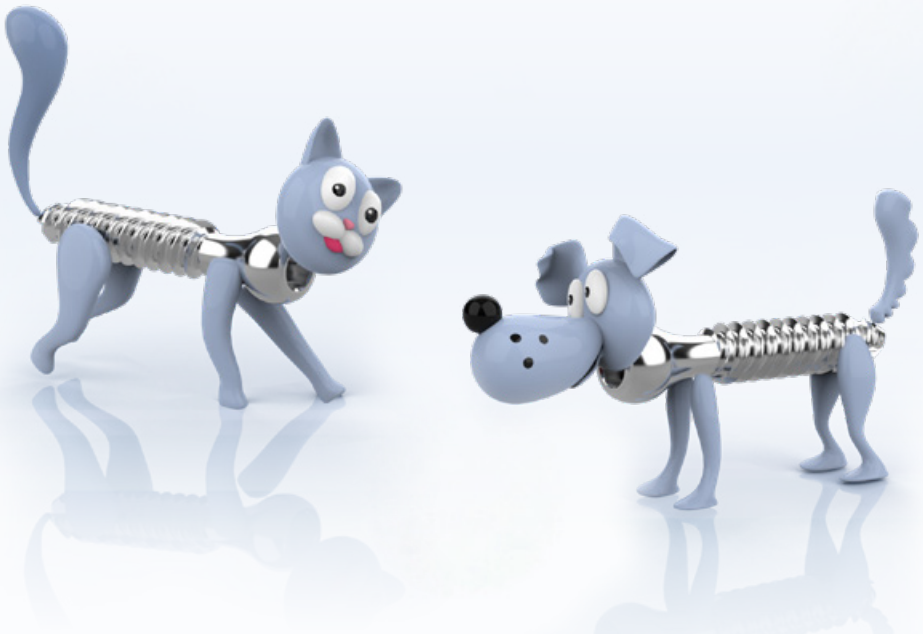
AGO MED

INSTRUCTION FOR USE

ORTHO-PEDIATRIC SYSTEMS



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REVISION 01

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PRODUCTS

- Multidirectional King-Kong Radius System 2.5
- Forefoot Plating Systems 2.7
- Rearfoot Plating Systems 3.5
- AGOMED-Pediatric System 3.5 / 4.0
- Mini Foot Plating System
- Cannulated standard screws
- Cannulated CBS Compression screws
- Cannulated interference 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 Pediatric System 3.5 / 4.0 is designed exclusively to redirect the growth angle of long bones, as this is useful for the gradual correction of angular growth deformities in growing children.

INDICATIONS

The AGOMED Pediatric System 3.5 / 4.0 is designed exclusively to redirect the growth angle of long bones, as this is useful for the gradual correction of angular growth deformities in growing children.

CONTRAINDICATIONS

Contraindications are closed joints and thus completed growth in this area. In post-infectious conditions, the result does not always seem to be predictable with certainty. This must be discussed explicitly during preoperative clarification. Even in cases of severe osteopenia, such as after prolonged cortisone therapy, the screws may sometimes not find sufficient hold in the bone. Nevertheless, in both cases, treatment can offer a therapeutic option before major invasive measures.

POSSIBLE ADVERSE EFFECTS OF THE IMPLANT SYSTEMS

The growth zone can be damaged if the screws penetrate it. To avoid this, the recommended implantation procedure must be used.

- The desired angular correction may fail or a possible overcorrection may occur.
- The plate may break or the bone screws may loosen, bend or break off.
- Replacement or removal of bone plates and bone screws may require a new operation.
- Complications due to metal sensitivity may occur.
- Danger from anesthesia and surgical intervention.

Taking into account the patient's clinical condition and medical history, the treating physician must ensure that the use of AGOMED 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.

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 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. Therefore, 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.

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

The screws must not be overtightened during insertion.

Overtightening can damage the screw head, lead to screw breakage and loss of the friction-locked tightness of the screw.

Overtightening of 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 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.

Usually AGOMED implants are designed for temporary use and can be removed after sufficient correction has been achieved.

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.

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, 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

REF **Item number**

LOT **Batch designation**

QTY **Quantity**

Follow the instructions for use

Not for reuse

Manufacturer

Date of manufacture

Store dry

Store away from direct sunlight

CE 0297 **DQS Medizinprodukte GmbH**
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60433 Frankfurt am Main