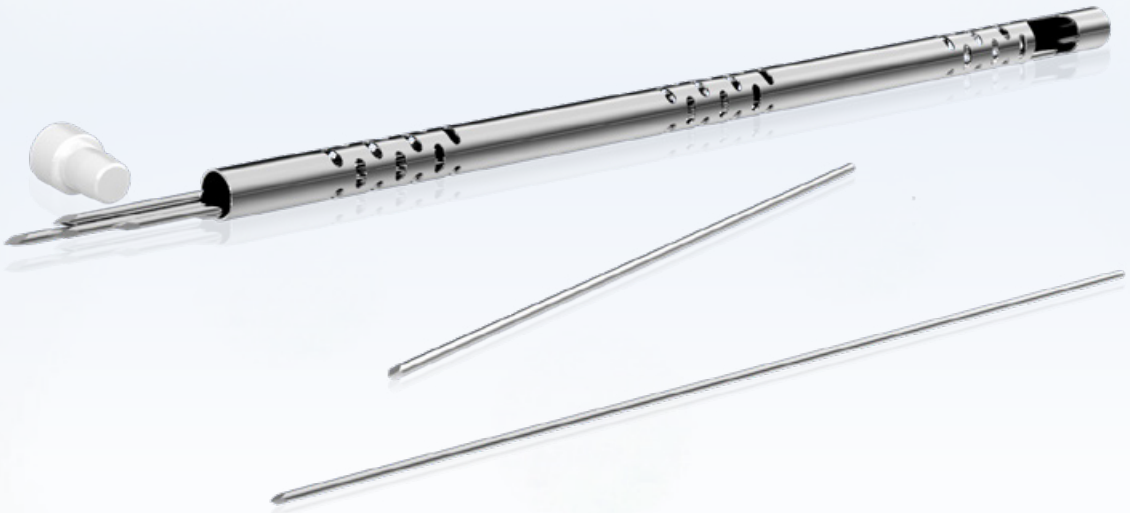
AGO MED

INSTRUCTION FOR USE

KIRSCHNER WIRES IMPLANTS



VALID FROM: 2020-07-21

REVISION 02

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IMPORTANT INSTRUCTIONS

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

Important instructions for use and further product-specific indications can be found in the respective surgical descriptions!

Carefully read the warnings marked by this symbol. Improper use of the products can lead to serious injuries to the patient, users or third parties.

Implants are designed for single use and not for reuse. All components are delivered UNSTERILE. They must be subjected to an appropriate reprocessing process before initial use. Before the reprocessing process, all packaging materials must be removed.

AREA OF APPLICATION

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

INTENDED USE

Wire implants are indicated for a wide range of orthopedic trauma applications, including:

- Stand-alone instrument for the fixation of fractures.
- Fracture fixation together with other fixation systems.
- Temporary fixation during open repositioning.

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.
- Growth plates must not be bridged.
- The combination of this implant with implants of other origin is contraindicated.

POSSIBLE ADVERSE EFFECTS OF THE IMPLANT SYSTEM

In many cases, undesirable results are not due to the implant but to clinical circumstances.

- Implant loosening.
- Massive bending and fracture of the implant.
- 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 pseudo arthrosis.
- Delayed, inadequate, or absent osseous remodeling of the fracture due to improper alignment may result in fracture of the implant.
- Increased fibrous tissue reaction around the surgical site.
- Early or late infections of a deep or superficial nature.
- Nerve damage as a result of surgical trauma.
- Metal hypersensitivity reactions in patients after implant placement have rarely been reported.

Taking into account the patient's clinical condition and medical history, the treating physician must ensure that the use of AGOMED wire 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 must not be reused.

The treating surgeon is responsible for the correct selection of patients, for the necessary training, the selection and placement of implants based on sufficient experience, and the decision to leave implants in place postoperatively 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. Postoperatively, the patient must feed on a passaged diet.

The surgeon should discuss in detail with the patient the surgical result to be expected when using this product. Particular attention should be paid to postoperative aspects, such as proper postoperative nutrition with a passed diet and the need for regular medical follow-up.

The selection of the correct product is extremely important. The product must be implanted in the correct anatomical position according to generally accepted standards of osteosynthesis. If an inappropriate product is used for the intended application, premature clinical implant failure may

occur. Failure to use the correct component to maintain adequate blood supply and rigid fixation may result in loosening, bending or fracture of the implant and/or bone.

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

An implant that has already been inserted once must not be reused under any circumstances. It may look undamaged on the outside, but previous stresses may have caused defects that can shorten the service life of the product.

All implants must be inspected before each clinical use.

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.

As a rule, AGOMED implants are designed for temporary use and can be removed after sufficient bony healing. Implants are not intended as long-term replacements for intact bone material. The usual duration of use of implants for mechanical support of osteosynthesis is between 30 days and 6 months.

In the case of suspected or diagnosed Creutzfeldt Jakob disease (CJD) or a variant of Creutzfeldt Jakob disease (vCJD), measures must be taken to prevent possible transmission to other patients, users and third parties. Country-specific reprocessing guidelines must be followed.

The products have not been tested under MRI environment. When used under MRI environment, the following risks may occur:

- Heating or migration of the implants.
- Artifact formation during MRI examinations.

USE OF ORIGINAL PRODUCTS

The implants and instruments are designed and manufactured to be precisely aligned with each other. The use of products from other manufacturers together with AGOMED products may be associated with unforeseeable risks and/or contamination of the material as well as misalignment of the implant and instrument, so that the patient, the user or third parties are endangered.

MATERIAL SPECIFICATIONS

- Stainless steel 1.4441
- Titanium Grade 4 (3.7065)
- Titanium Grade 5 (3.7165)

All materials are biocompatible, corrosion resistant, and non-toxic in the biological environment, enabling artifact-free imaging.

STORAGE


The products must be protected from direct sunlight during storage.


The products must be stored in a dry place.

PREPARATION

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

When selecting the cleaning agents, disinfectants and equipment used, care must be taken at all steps to ensure that:

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

With the aid for cleaning, both in the pre-cleaning must be ensured that:

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

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

Automatic cleaning process:
Pre-cleaning

Step	Time (Min)	Process	Cleaning agent	Temp. (°C)
1	-	If threaded, brush three times in tap water with bottle brush	Tap water	Cold (20°±2)
2	2	Rinse under running water	Deionized water	Cold (20°±2)

Machine cleaning

Step	Time (Min)	Process	Cleaning agent	Temp. (°C)
1	2	Pre-cleaning	Tap water	Cold (16°±2)
2		Emptying		
3	5	Cleaning	Tap water; 0.5% alkaline cleaning (Mediclean fortet)	55
4		Emptying		
5	3	Rinsing	Deionized water	Cold (20°±2)
6		Emptying		
7	2	Flushing	Deionized water	Cold (20°±2)
8		Emptying		

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. The thermal disinfection corresponds to the A0 concept (A0 value 3000). The thermal disinfection is to be carried out by means of the following parameters:

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

MANUAL DISINFECTION

- Placing the cleaned and controlled products in 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 observed.
- Moving parts back and forth several times.
- Rinsing 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 no visible contamination remains.
- The products must be completely dried immediately afterwards (drying with compressed air is recommended).
- Check the products.
- Pack the products as soon as possible, if necessary after additional subsequent drying.

CONTROLLING

Check all implants after cleaning and disinfection for damage, contamination and to 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 min., drying at least 20 min.

Or

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

EXPLANATION OF SYMBOLS

Article number

Batch designation

Quantity


Observe instructions for use


Not for reuse


Manufacturer


Date of manufacture


Store in a dry place


Store away from direct sunlight

CE 0297

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