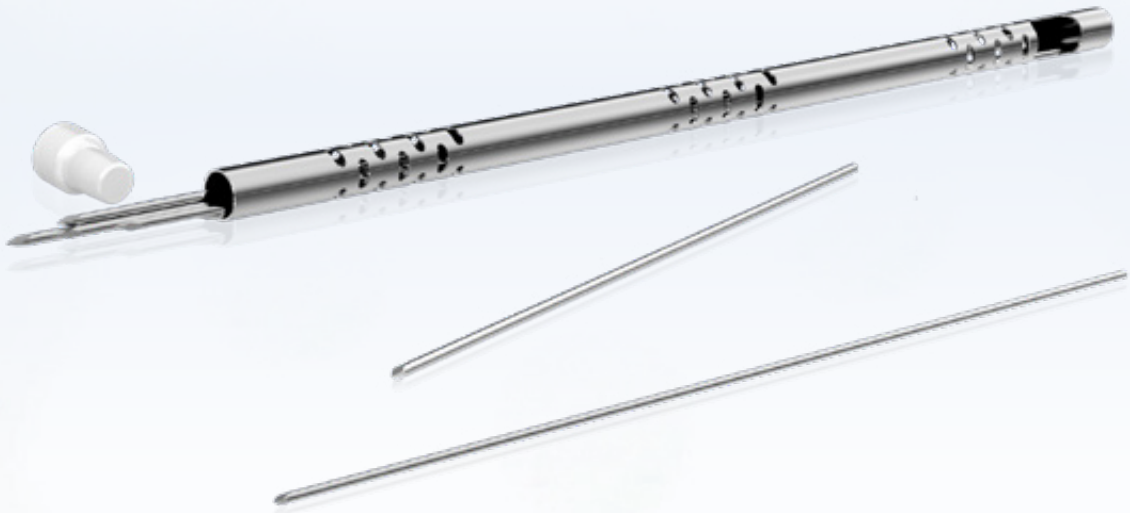
AGO MED

INSTRUCTION FOR USE

KIRSCHNER WIRES



VALID FROM: 2020-03-10

REVISION 01

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PRODUCTS

This instruction manual is valid for all Agomed wire implants.

IMPORTANT NOTE

Read these instructions for use carefully and keep them easily accessible.

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.

1. PRECAUTIONS AND WARNINGS

CREUTZFELDT- JAKOB DISEASE

If Creutzfeldt-Jakob disease (CJD) or a variant of Creutzfeldt-Jakob disease (vCJD) is suspected or diagnosed, measures must be taken to prevent possible transmission to other patients, users and third parties. The country-specific reprocessing guidelines must be observed.

MRI ENVIRONMENT

The products have not been tested in an MRI environment. The following risks may occur when used in an MRI environment:

- Heating or migration of the implants
- Artifact formation during MRT examinations

POSTOPERATIVE AFTERCARE

The attending physician must inform the patient about the load limitations of the implant and provide a plan for postoperative behavior and increased physical stress. Failure to do so may result in malalignment, delayed bone healing, implant failure, infection, and/or wound hematoma.

2. INTENDED USE

2.1 INDICATION

Wire implants are indicated for a wide range of applications in orthopedic trauma surgery:

- Single implant for fracture fixation
- Temporary intraoperative fixation of fracture fragments
- Fracture fixation in combination with other fixation systems

2.2 CONTRAINDICATION

- Acute infection
- Malignant primary or metastatic tumors that preclude adequate bone support or screw fixation unless additional fixation or stabilization methods are used.
- Conditions that slow down bone healing, such as restrictions in blood supply, previous infections, etc.
- Insufficient quantity or quality of bone for osteosynthesis Procedure
- Conditions that limit the patient's ability or willingness to follow postoperative instructions during the healing process
- Metal hypersensitivity
- Obesity

2.3 KNOWN RISKS AND SIDE EFFECTS

- Emigration of the wires
- Wire break
- Implant failure if no additional immobilization is performed

3. MATERIAL SPECIFICATIONS

Agomed bone implants are made of commercially available titanium, titanium alloys and implantable corrosion-resistant steel. The materials are biocompatible, corrosion resistant and non-toxic in the biological environment and allow virtually artifact-free X-ray and CT imaging.

4. LIABILITY AND WARRANTY

Agomed Medizin-Technik GmbH, as the manufacturer, is not liable for consequential damages resulting from improper use or handling. This applies in particular to non-compliant use or disregard of the reprocessing and sterilization instructions. This also applies to repairs or modifications to the product carried out by unauthorized personnel of the manufacturer. These exclusions of liability also apply to warranty services.

5. GENERAL WARNINGS AND PRECAUTIONS

For single use only. Products for single use only must not be reused, because according to their design they will not function as intended after the first surgical use. Changes in mechanical, physical or chemical properties due to repeated use may affect the design and/or materials, resulting in reduced safety, performance and/or compliance with the specifications in the accompanying documentation.

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 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.

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 postoperative aspects, such as the need for regular medical follow-up.

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

6. STERILITY

DELIVERY CONDITION

The Kirschner wires are delivered in non-sterile condition and must be prepared and sterilized by the user according to the following instructions before use.

7. APPLICATION AND SERVICE LIFE

The products are intended for single use. Removal is performed after the bone healing process is complete (after approx. 4-6 weeks).

If the K-Wires are used temporarily for fixation, they must be removed after attachment of the final osteosynthesis.

8. PREPARATION

WARNINGS

- Frequent reprocessing impairs the quality of the products.
- City water to be used must be of the same quality as drinking water for human consumption.
- This reprocessing instruction specifies the cleaning and disinfecting agents used for validation. If an alternative detergent and disinfectant (RKI or VAH listed) is used, the responsibility lies with the reprocessor.

PLACE OF USE

The first steps of a correct preparation already start in the operating room.

Coarse soiling, residues of e.g. haemostatic agents, skin disinfectants and lubricants as well as corrosive drugs should be removed, if possible, before placing the implants.

Wherever possible, dry disposal (moistened, closed system) is to be preferred. Drying of residues should be avoided!

Long waiting times for preparation, e.g. overnight or over the weekend, should be avoided with both types of disposal (<6 hours).

TRANSPORT

The products must be disposed of dry immediately after use. This means that the products have to be transported moist in a closed container from the place of application to the processing plant, so that the products do not dry out.

PREPARATION FOR DECONTAMINATION

The products must be prepared in suitable sieve baskets or rinsing trays (select size according to product). The products should be fixed in the cleaning basket with a minimum distance between them. Overlapping should be avoided in order to prevent the products from being damaged by the cleaning process.

PRE-CLEANING

Rinse products under cold city water of drinking water quality (<40°C) until all visible contamination is removed. Solid dirt must be removed with a soft brush. Instruments must be rinsed intensively (>10 sec) with cold city water of drinking water quality (<40°C) using a water pressure gun (4 bar).

If visible soiling remains after pre-cleaning, the products must be further treated using ultrasonic cleaning. During this process, place the instruments in cold water for 5 minutes. Place the products in an alkaline cleaner (0.5% neodisher FA) in an ultrasonic bath with a sonication time of 10 minutes and a frequency of 35 kHz. Follow the instructions of the detergent manufacturer.

Instruments must be rinsed intensively (>10 sec) with cold city water of drinking water quality (<40°C) using a water pressure gun (4 bar).

CLEANING / DISINFECTION

Automatic cleaning / disinfection process

(Washing machine G 7735 CD Miele):

- 1 minute pre-cleaning with cold city water Drinking water quality <40°C
- Water drain
- 3 minutes pre-cleaning with cold city water Drinking water quality <40°C
- Water drain
- 5 minutes cleaning at 55°C±5°C with 0.5% alkaline detergent (0.5% Neodisher FA)
- Water drain
- 3 minutes neutralization (0.1% Neodisher® Z) with cold city water Drinking water quality <40°C
- Water drain
- 2 minutes rinse with deionized water <40°C

The special instructions of the manufacturer of the cleaning machine must be observed.

Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account national requirements for A0 value; e.g. A0- value 3000:

>5 minutes at 92°C±2°C
with VE water.

Automatic Drying

Automatic drying according to the automatic drying process of the washer-disinfector for at least 30 minutes (at 60°C±5°C in the rinsing room). If necessary, subsequent manual drying with lint-free cloth and blowing out of lumens using sterile, oil-free compressed air.

STERILIZATION
Sterilization of the products using fractionated pre-vacuum processes (according to DIN EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging.

Sterilization is to be carried out using a fractionated pre-vacuum process with the following parameters:

temperature 132°C
≥3 minutes hold time,
3 pre-vacuum cycles
Drying in vacuum for at least 20 minutes

Flash sterilization is not suitable for products with lumen!

The instructions for use of the autoclave manufacturer and the recommended guidelines for maximum loading with sterilization material must be observed. The autoclave must be properly installed, maintained, validated and calibrated.

ADDITIONAL INFORMATION
It is the responsibility of the processor to ensure that the actually performed reprocessing with used equipment, materials and personnel in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and the equipment used.

9. SERVICE AND REPAIR

SERVICE AND REPAIR
Do not carry out any repairs or changes to the product yourself. Only authorized personnel of the manufacturer are responsible for and intended for this. If you have any complaints, claims or suggestions regarding our products, please contact us.

RETURN TRANSPORT
Defective or non-compliant products must have gone through the entire reconditioning process before being returned for repair/service.

10. PACKAGING, STORAGE AND DISPOSAL

Standardized packaging of products for sterilization according to ISO 11607 and EN 868.

Store sterile products in dry, clean and dust-free environment, protected from damage, at moderate temperatures.

The manufacturer's medical products should be stored and kept in individual packages, boxes or protective containers. Please handle the instruments with the utmost care during transport, storage and reprocessing. The maintenance of the sterile condition after the sterilization process is to be ensured by the user or the designated specialist personnel.

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws. The manufacturer does not provide specific instructions for this.

11. DESCRIPTION OF SYMBOLS USED

Attention!

Observe operating instructions

Date of manufacture

Do not reuse

REF **Artikelnummer Item number**

LOT **Chargenbezeichnung Batch designation**

CE 0297 **CE-Kennzeichen CE Marking**

The sale or prescription of this device by a physician is subject to restrictions under federal law

NON STERILE **Specification for non-sterile product**

Name and address of the manufacturer