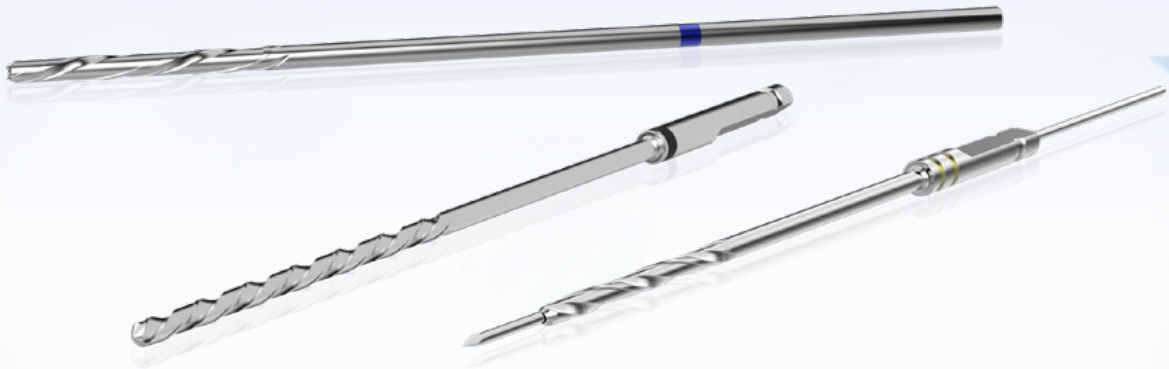
AGO MED

INSTRUCTION FOR USE

TWIST DRILLS, CANNULATED DRILLS AND ALL ROTARY INSTRUMENTS



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REVISION 03

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PRODUCTS

These Preparation Instructions are valid for all Agomed twist drills, cannulated drills and all rotary instruments.

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. DEVICE DESCRIPTION

A twist drill is a powered medical tool used in surgery to drill holes in bone. The diameter of the twist drill results from the core diameter of the desired screw. The twist drill has a conical head and two cutting edges, each consisting of a main cutting edge, a secondary cutting edge and a transverse cutting edge. The head is pointed with a typical point angle. There are several important angles on the twist drill. The so-called side rake angle indicates the pitch of the helix. It also corresponds to the rake angle at the edge of the drill. However, the rake angle changes across the diameter. In the center, where the main cutting edge merges with the cross cutting edge, it becomes strongly negative. The point angle corresponds to the double tool setting angle and indicates the angle of the two main cutting edges.

A countersink is a powered medical tool used to cut a tapered hole. A common use is to make the head of a countersunk screw sit flush with or below the surface of the bone. A countersink can also be used to remove the burr created by drilling or tapping, improving the surface of the product and removing dangerous sharp edges.

2. INTEDED USE

The rotary instruments are designed for the preparation of bone during osteosynthesis procedures. The functions include drilling, milling and cutting of bones.

2.1 INDICATION

The indications/contraindications refer to the implants and not to the instruments. Specific indications/contraindications for the implants can be found in the respective instructions for use of Agomed implants.

2.2 CONTRAINDICATION

No contraindications known.

2.3 COMPLICATIONS AND SIDE EFFECTS

- Heat development due to the drilling process
- Injury to bone and surrounding tissue

3. 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.

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. STERILITY

DELIVERY CONDITION
Spiral and cannulated drills are delivered in non-sterile condition and must be prepared and sterilized by the user according to the following instructions before the first and each subsequent application.

6. LIFETIME OF THE PRODUCTS

The service life depends on the wear and tear and the frequency of use. Before each use of the instruments, they must be inspected for fractures, cracks, deformations, damage and functional efficiency. Areas such as cutting edges and tips must be checked particularly carefully. Worn, corroded, deformed or otherwise damaged instruments must be sorted out. The stainless steels used for instrument manufacture (non-rusting, “stainless”) form specific passive layers as protective layers due to their alloy. These steels have only limited resistance to attack by chloride ions and aggressive media and liquids!

7. 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 begin in the operating room.

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

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

Long waiting times for reprocessing, 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 deionized 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.

8. 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.

9. 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.

10. DESCRIPTION OF SYMBOLS USED

Attention!

Observe operating instructions

Date of manufacture

REF **Item number**

LOT **Batch designation**

CE 0297 **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