INSTRUCTIONS FOR USE

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Instruments

These Instructions for Use and all of the products mentioned in these Instructions for Use relate exclusively to medical devices from *aap* Implantate AG. Products as defined above are instruments (class I, Im and Ir instruments, twist drills and countersinks) that are needed for surgery. The products may be used only by appropriately trained medical staff according to the principles of fracture management of the AO Foundation.

The Instructions for Use also apply to all products used together.

aap instruments are made of stainless steel, plastic, aluminum, or titanium.

1 Intended Use

Instruments (class I, Im, Ir)

Surgical instruments are intended to aid in the insertion of bone plates and screws as well as for reduction and support during orthopedic surgeries. If not otherwise specified, instruments are intended for multiple use.

Twist drills

Drills are intended for drilling pilot holes in large and small bone during orthopedic surgery, to enhance insertion of bone screws.

Countersinks

Countersinks are intended for drilling holes in large and small bone during orthopedic surgery, to countersink screws into the bone.

2 Indications for use

The instruments themselves have no indications. They are intended to be part of a complete system consisting of *aap* implants and *aap* instruments. The indication for the system is listed in the associated Instructions for Use.

3 Absolute contraindications

The instruments themselves have no contraindications. The contraindications depend on the relevant implant system. The products are only intended for use with *aap* implants and are contraindicated for all applications outside of the intended use.

In the event of any incidents with *aap* products, these must be reported immediately via incident@aap.de. The products involved must be seized for further testing.

aap will not accept the return of other implants used.

4 Handling, warnings and precautions

Preoperative:

When removing implants from the package always check product integrity and matching with the specifications on the printed label. Damaged products should not be used. *aap* is only liable for the products as supplied. Any unintended modification will result in a new medical device for which the operator (clinic, practice, etc.) then becomes liable.

The use of products is described in detail in the relevant surgical technique. This can be accessed through *aap* or online at *www.aap.de*.

The products are marketed by *aap* in non-sterile and sterile condition and are labeled accordingly. Products labeled non-sterile must be appropriately processed before use (see the chapter on “Processing of products”).

Caution

The use of *aap* products with products and/or accessories from other manufacturers has not been tested by *aap* and is excluded.

Only for Germany: The proper condition and the function of the measuring instruments and the legibility of the scale on the measurement devices must be regularly monitored as part of medical and technical control (according to MPBetriebV [Medical Device Operating Regulation], Section 11, paragraph 1).

Intraoperative:

Twist drills are marketed as reusable products and single-use products and are labeled accordingly.

Caution

Reusable products can wear out as a result of use and lose their function. The integrity of the products must therefore be checked before each use. Worn out or functionally impaired products must be disposed of immediately. *aap* does not accept any liability for damage caused by a lack of or by irregular checks on the products, in particular the drill.

Cannulated products must be cleaned regularly during surgery using a cleaning wire to ensure that an accumulation of tissue residue in the lumen does not impair function.

Surfaces can wear through repeated use and processing so direct labeling on the product is no longer legible. If information applied to the item (e.g. catalogue number, functional label, symbols) can no longer be clearly read, the product must be replaced immediately.

If twist drills or countersinks are used with motorized devices, the Instructions for Use of all jointly used products also apply.

The following should be ensured:

- Instruments should be inserted to the stop
- The secure positioning of the instrument must be checked before it is put into operation
- Levering and tilting should be avoided
- Excessive contact pressure should be avoided and sufficient cooling must be ensured
  - to avoid premature failure
  - to avoid increased generation of heat (thermal necrosis)
  - to avoid functional impairment, particularly of cutting
  - to achieve a longer service life

Instruments with measurement functions have the following measurement accuracies or reading accuracies

Medical device with measurement function	Measurement accuracy
Depth measurement on the drill via drill guide: IU 8166-10/20 + IU 7427-16(-1U), IU 7427-23(11U); IU 8167-10/20 + IU 7438-18(-1U), IU 7438-20(-1U), IU 7438-22(-1U), IU 7438-25(-1U), IU 7438-33(-1U)	± 0.5 mm
Depth measurement on the drill guide with scale and drill: IU 8165-22 + IU 7420-11(-1U); IU 8166-30 + IU 7423-18(-1U); IU 8168-20 + IU 7420-10(-1U); IU 8169-20 + IU 7420-16(-1U), IU 7420-18(-1U)	± 0.55 mm
Wedge gauge for osteotomy: IU 7960-00	± 0.7 mm
Chisel with scale: IU 3000-15, IU 3000-20	± 0.2 mm
Measurement instrument (depth gauge): IS 7903-10, -20, -30, -40; IS 7904-20; IS 7905-20	± 0.2 mm
Measuring device for K-wire: IS 7910-00, IS 7915-03, IS 7927-01, IU 7915-02, IU 7915-10, IU 7920-02, IU 7922-00, IU 7925-20, IU 7927-00, IU 7927-10	± 0.7 mm
Depth gauge for femur MIS: IU 7940-00	± 0.5 mm
Ruler for DF (PP): IU 7902-00	± 0.5 mm
Angle gauge for closed wedge osteotomy: IU 7970-00	± 0.77°

The measuring instruments can be used together with the intended implant system and adjusted to this. The accuracy of the measuring instruments has been designed to be sufficient for their intended use (e.g. determination of screw length). Please note the relevant surgical technique.

Caution

Drill guides are used to protect plates and soft tissue during drilling.

Moving or sharp instrument parts (e.g. forceps) may cause injuries, clamping or piercing of surgical gloves.

Always seat the screwdriver fully into the screw head and align its shaft with that of the screw.

5 Processing of products

In order to ensure that the value of the products is maintained, this processing recommendation and the relevant national laws and standards must be complied with. All products must be cleaned and disinfected before sterilization.

Protective films and caps, as well as any other protective devices, must be removed completely before processing. Trays by *aap* are intended for the sterilization, transport and storage of products. They are not intended for cleaning and disinfection when filled. The products must be removed from the trays and cleaned and disinfected separately.

For the USA: Only use FDA-approved sterilizers and FDA-approved sterilization accessories.

aap recommends the following procedures and their parameters as well as the following sequence:

① Manual precleaning → ② Automated cleaning/Disinfection process → ③ Care/Check → ④ Packing → ⑤ Saturated steam sterilization

Description of the procedure:

① Manual precleaning

- Visible contamination must be removed within the first hour of using the products.
- Products that can be disassembled must be dismantled, sliding shaft instruments must be fully opened and scissors and forceps opened to a 90° angle in order to clean as much of the hidden surfaces as possible.
- The products must be put into cold water and brushed under the surface of the water using a cleaning brush (e.g. Interlock, REF 09098) until the surface is visibly clean.
- Instruments with cavities must be cleaned with a round brush that fits inside the lumen. This step should take 2 minutes and should be repeated 3 times.
- *aap* recommends using ultrasonic bath treatment for coarse soiling.
- In addition, a syringe or high-pressure water gun should be used to rinse cavities, blind holes, notches and channels with cold tap water for at least 30 seconds. Contact between products and the syringe or high-pressure water gun should be avoided to rule out scratches.
- Let the products drain and go on to the next cleaning step.

② Automated cleaning/disinfection process

- When selecting the cleaning program, it is necessary to consider the material of the medical devices to be cleaned and the appliance manufacturer’s instructions.
- Products must be inserted into the appliance in such a way as to ensure that they are rinsed through.
- It is necessary to rinse for at least 60 seconds in cold tap water.
- It is then necessary to clean for 10 min with "Neodisher® MediClean forte" (Dr. Weigert) at a dosage of 5 ml/l (pH >10.0 to 11.5) at 55 °C.
- It is necessary to rinse for at least 60 seconds in cold, deionized tap water.
- Thermal disinfection should be carried out according to the A_0 concept in accordance with DIN EN ISO 15883-1 (according to the recommendation by the KRINKO Commission at the Robert Koch Institute the A_0 value should be 3000).
- Drying should be carried out automatically at 110 °C for at least 20 minutes.

③ Care/Check

- Once the cleaning and disinfection cycle is complete, the products must be cooled to room temperature.
- Residue and residual moisture should be prevented by means of a visual inspection of the critical places (cavities, blind holes, notches and channels).
- Damaged and defective products should be rejected and replaced.

④ Packing

- Products with delicate working ends must be stored in suitable supports.
- The trays provided by *aap* should be used; otherwise, universal sterilization trays should be used in compliance with the manufacturer's instructions.

⑤ Saturated steam sterilization

For the USA: Only use FDA-approved sterilizers and FDA-approved sterilization accessories.

- Cycle type: full cycle with fractionated pre-vacuum process
- Set points for the parameters:
  - Exposure temperature:
    - for the CE area: 134 °C (273 °F)
    - for the FDA area: 270 °F (132 °C)
  - Exposure time: 4 minutes
  - Drying time: 20 minutes continuously or fractionated drying procedure

This information is provided without guarantee. The aforementioned instructions were validated by *aap* as being suitable for the processing of the products for use but cannot replace detailed process descriptions because we cannot provide a detailed description of the variety of processing procedures used worldwide. The processor is responsible for the desired result in the actual processing using equipment, materials and personnel in the processing facility. To achieve this, validation and routine inspections of the process on site are required. Any elements that may affect the structure, functionality and product identification (e.g. unnecessary vibration, strain, moisture, heat and UV radiation) must be minimized by the user.

6 Packaging, sterility, storage and shipping conditions

Sterile packed products

The products are sterilized with gamma radiation. The packaging system consists of a sterile barrier system (double packaging) in protective packaging. The protective packaging contains labels which can be used for patient documentation to ensure the traceability of the products.

Storage and shipping conditions:

Type	Condition	Temperature range	Humidity	Max. duration
Sterile packed products	Shipping	0 °C to 60 °C	<70%	6 days
	Storage	15 °C to 23 °C	<70%	until the expiration date*

* If the storage conditions indicated are exceeded, a time-bound upper limit equivalent to the shipping conditions applies: temperature range 0 °C to 60 °C with maximum humidity of 70% for a maximum of 3 whole days.

Sterile packed products must be stored in their sealed original packaging. They should be stored protected from dust and in a clean, dry place out of direct sunlight. Opening the protective packaging (breaking the seal) is deemed to be equivalent to using the contents.

The sterile barrier must be checked for defects before opening. If defects of any kind are identified, the products should not be used. The sterile packaging may only be opened during surgery according to the hospital regulations. The products must be subjected to a visual inspection before they are used. Products with defects of any kind must be disposed of.

The expiration date must always be checked before the packaging is opened. If the expiration date has passed, the products should not be used.

7 Symbol definitions

	Non-sterile		Do not re-use
	Date of manufacture		Consult Instructions for Use
	Manufacturer		Caution—refer to enclosed documentation
Qty.	Number of products	REF	Catalogue number
	Caution: Federal law restricts these devices to sale by or on the order of a physician (USA).	LOT	Lot number
STERILE R	Sterilization by gamma radiation		Temperature limit
	Do not resterilize		Humidity limitation
	Use by date		Keep away from sunlight
	Protect against moisture		Do not use if package is damaged
CE	Labeling for class I and class Ir medical devices	CE 0124	Labeling for class Im or class IIa medical devices

INSTRUCTIONS FOR USE

EN

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TORQUE LIMITER

These Instructions for Use and all of the products mentioned in these Instructions for Use relate exclusively to medical devices from *aap* Implantate AG. Products as defined above are instruments (class I, Im and Ir instruments, twist drills and countersinks) that are needed for surgery. The products may be used only by appropriately trained medical staff according to the principles of fracture management of the AO Foundation.

The Instructions for Use also apply to all products used together.

1 Intended use

Torque limiters are used to limit the transmitting torque to a defined level when inserting locking screws.

2 Indications for use

The instruments themselves have no indications. They are intended to be part of a complete system consisting of *aap* implants and *aap* instruments. The indication for the system is listed in the associated Instructions for Use.

3 Absolute contraindications

The instruments themselves have no contraindications. The contraindications depend on the relevant implant system. The products are only intended for use with *aap* implants and are contraindicated for all applications outside of the intended use.

In the event of any incidents with *aap* products, these must be reported immediately via *incident@aap.de*. The products involved must be seized for further testing.

aap will not accept the return of other implants used.

4 Handling, warnings and precautions

Preoperative:

When removing implants from the package always check product integrity and matching with the specifications on the printed label. Damaged products should not be used. *aap* is only liable for the products as supplied. Any unintended modification will result in a new medical device for which the operator (clinic, practice, etc.) then becomes liable.

The use of products is described in detail in the relevant surgical technique. This can be accessed through *aap* or online at *www.aap.de*.

aap markets unsterilized products which are appropriately labeled and must be appropriately processed before use (see the chapter on “Processing of products”).

Before surgery, the surgeon must be well versed in the general surgical procedure, particularly in the surgical technique required for the products used. Correct choice and placement of products is crucial. Instructions on product combinations are included in the description of the pertinent surgical technique. Caution

The use of aap products with products and/or accessories from other manufacturers has not been tested by aap and is excluded.

Intraoperative:

The torque limiter may only be used for tightening orthopedic or trauma products, but not for loosening screws since this may lead to damage. As soon as tightening has reached the torque limit, the torque limiter will disengage with an audible "click", thus preventing the transmission of higher torques than those set by the manufacturer. In order to ensure accuracy, the instrument may only be used manually.

Accuracy of the factory-fresh torque limiter:

- ± 10%

Service life of the torque limiter

The torque limiter is intended for time-limited use and can be reused within its service life. Service life ends after three years or after approx. 6,000 clicks or 250 sterilization cycles. The operator is responsible for monitoring service life and must ensure that the torque limiter is disposed of once the service life ends.

aap does not accept any liability for damage caused by a lack of or by irregular checks on the products.

Caution

Reusable products can wear out as a result of use and lose their function. The integrity of the products must therefore be checked before each use. Worn out or functionally impaired products must be disposed of immediately. *aap* does not accept any liability for damage caused by a lack of or by irregular checks on the products, in particular the drill.

Surfaces can wear through repeated use and processing so direct labeling on the product is no longer legible. If information applied to the item (e.g. catalogue number, functional label, symbols) can no longer be clearly read, the product must be replaced immediately.

5 Processing of products

In order to ensure that the value of the products is maintained, this processing recommendation and the relevant national laws and standards must be complied with. All products must be cleaned and disinfected before sterilization.

Protective films and caps, as well as any other protective devices, must be removed completely before processing. Trays by *aap* are intended for the sterilization, transport and storage of products. They are not intended for cleaning and disinfection when filled. The products must be removed from the trays and cleaned and disinfected separately.

For the USA: Only use FDA-approved sterilizers and FDA-approved sterilization accessories.

aap recommends the following procedures and their parameters as well as the following sequence:

① Manual precleaning → ② Automated cleaning/Disinfection process → ③ Care/Check → ④ Packing → ⑤ Saturated steam sterilization

Description of the procedure:

① Manual precleaning

- Visible contamination must be removed within the first hour of using the products.
- Products that can be disassembled must be dismantled, sliding shaft instruments must be fully opened and scissors and forceps opened to a 90° angle in order to clean as much of the hidden surfaces as possible.
- The products must be put into cold water and brushed under the surface of the water using a cleaning brush (e.g. Interlock, REF 09098) until the surface is visibly clean.
- Instruments with cavities must be cleaned with a round brush that fits inside the lumen. This step should take 2 minutes and should be repeated 3 times.
- *aap* recommends using ultrasonic bath treatment for coarse soiling.
- In addition, a syringe or high-pressure water gun should be used to rinse cavities, blind holes, notches and channels with cold tap water for at least 30 seconds. Contact between products and the syringe or high-pressure water gun should be avoided to rule out scratches.
- Let the products drain and go on to the next cleaning step.

② Automated cleaning/disinfection process

- When selecting the cleaning program, it is necessary to consider the material of the medical devices to be cleaned and the appliance manufacturer’s instructions.
- Products must be inserted into the appliance in such a way as to ensure that they are rinsed through.
- It is necessary to rinse for at least 60 seconds in cold tap water.
- It is then necessary to clean for 10 min with "Neodisher® MediClean forte" (Dr. Weigert) at a dosage of 5 ml/l (pH >10.0 to 11.5) at 55 °C.
- It is necessary to rinse for at least 60 seconds in cold, deionized tap water.
- Thermal disinfection should be carried out according to the A_0 concept in accordance with DIN EN ISO 15883-1 (according to the recommendation by the KRINKO Commission at the Robert Koch Institute the A_0 value should be 3000).
- Drying should be carried out automatically at 110 °C for at least 20 minutes.

③ Care/Check

- Once the cleaning and disinfection cycle is complete, the products must be cooled to room temperature.
- Residue and residual moisture should be prevented by means of a visual inspection of the critical places (cavities, blind holes, notches and channels).
- Damaged and defective products should be rejected and replaced.
- After the cleaning and disinfection cycle, all of the treads and joints etc. need to be lubricated with white medical oil.

④ Packing

- Products with delicate working ends must be stored in suitable supports.
- The trays provided by *aap* should be used; otherwise, universal sterilization trays should be used in compliance with the manufacturer's instructions.

⑤ Saturated steam sterilization

For the USA: Only use FDA-approved sterilizers and FDA-approved sterilization accessories.

- Cycle type: full cycle with fractionated pre-vacuum process
- Set points for the parameters:
  - Exposure temperature:
    - for the CE area: 134 °C (273 °F)
    - for the FDA area: 270 °F (132 °C)
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Any elements that may affect the structure, functionality and product identification (e.g. unnecessary vibration, strain, moisture, heat and UV radiation) must be minimized by the user.

1 Definition of symbol

NON STERILE	Non-sterile		Do not re-use
	Date of manufacture		Consult Instructions for Use
	Manufacturer		Caution—refer to enclosed documentation
Qty.	Number of products	REF	Catalogue number
CE	Labeling for class I and class Ir medical devices	LOT	Lot number
℞ ONLY	Caution: Federal law restricts these devices to sale by or on the order of a physician (USA).		