EN - universal ratchet without torque with optional flexible rod attachment – instructions for use

REF **Ratchet no. 1000603, 1000604, 1000605, 1000606 and optional flexible rod attachment no. 1010623, 1010624, 1010625, 1010626**

NON STERILE CE

Important note

Read these instructions for use carefully prior to each application, and store them so that they are easily accessible for the user or relevant specialist personnel.

Carefully read through the warning information marked with this symbol. Improper use of the devices can lead to serious injury to the patient, the user or third parties.

1 Intended use

1.1 Intended use/indication

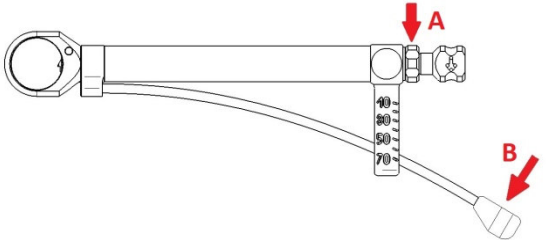
Ratchet for inserting and removing dental screws and implants with a defined torque. The torque ratchet must only be used by trained dental specialists. It can be used with or without the flexible rod attachment.

1.2 Contraindications

Specific contraindications for the torque ratchet must be considered exclusively in combination with the overall surgical procedure.

2 Handling

2.1 Prosthodontic setting – torque function: Application with the flexible rod attachment. The torque is read out via the flexible rod, using the scale.

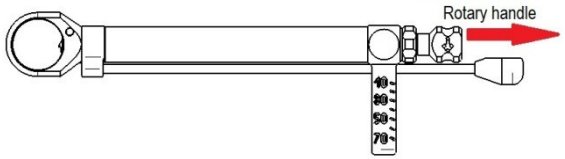


Apply pressure to the component at **arrow B**.
The required torque is reached when the centre of the flexible rod is in line with the corresponding scale marking.
PLEASE NOTE! Always read out the value from directly above.
PLEASE NOTE! Only exert strain on the flexible rod up to the last scale value.

Release the strain again when the required torque is reached. The flexible rod will then spring back to the starting position.

2.2 Surgery setting − blocked function: Using the ratchet without the flexible rod.
Apply pressure to the component at **arrow A**. **PLEASE NOTE!** The ratchet without flexible rod must not be subjected to stress of over 100 Ncm.

3 Changing the rotation direction



- Pull the rotary handle
- Rotate the rotary handle by half a turn
- Release the rotary handle again

4 Replacing tools/inserts/ratchet wheels

Pull the rotary handle; tools can be removed or inserted. Release the rotary handle again. Tools can be inserted from both sides. Change the rotation direction as required.

5 Materials

The universal ratchet without torque and with optional flexible rod attachment is made from stainless steels (1.4305, 1.4197, 1.4310).

6 Precautions and warnings

Please note!
The torque ratchet with flexible rod is designed exclusively for dental applications, and must not be used for any other purpose. Improper handling and care and use other than for the intended purpose can lead to premature wear to the approximator.

Material incompatibility
The medical devices must not under any circumstances be used if the user or the specialist personnel becomes aware that the patient has material incompatibilities.

Functional impairment
Surgical instruments may corrode and suffer from impaired functioning if they come into contact with aggressive substances. For this reason, it is essential that the reprocessing and sterilisation instructions be followed.

Operation conditions
In order to guarantee safe operation of the devices detailed above, they must be cared for and maintained correctly. A function test or visual inspection must also be carried out before each use. To this end, we therefore refer to the relevant sections of these instructions for use.

Storage
There are no special requirements regarding storage of the devices. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

7 Sterility

NON STERILE

The medical devices are delivered in non-sterile condition and must be reprocessed and sterilised by the user before the first use and before each subsequent use in accordance with the instructions below.

8 Service life

When the torque to be set has been reached 5000 times, the lifetime ends.
As the medical devices from Josef Ganter Feinmechanik GmbH are made from resistant, tried-and-tested materials in the field of medical technology, it is not possible to define an exact service life. The service life is based on the wear and the frequency of use. The information on function testing prior to use should be taken into consideration in this regard.

9 Reprocessing

Warning information

- Frequent reprocessing will impair the quality of the devices.
- Any water that is used must be of drinking-water quality.
- These reprocessing instructions set out the cleaning agents and disinfectants used for validation. If an alternative cleaning agent or disinfectant is used (as listed by the German Association for Applied Hygiene (VAH) or the Robert Koch Institute (RKI)), the responsibility lies with the person carrying out reprocessing.

9.1 Place of use

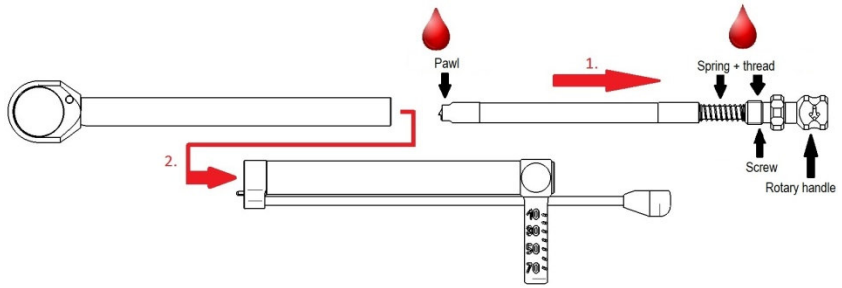
The first steps towards correct reprocessing are taken in the operating theatre.
Wherever possible, heavy contamination and residues of substances such as filling materials, disinfectants or other medications should be removed before putting away the instruments.
Dry disposal (moistened, closed system) is preferred if possible. The drying on of residues should be avoided!
Long waiting times prior to reprocessing, e.g. overnight or over the weekend, should be avoided with both disposal methods (<6 hours).

9.2 Transportation

The devices must be disposed of after use by means of dry disposal. This means that the devices must be transported for reprocessing from the place of use, moistened and in a closed container to prevent the risk of contamination becoming dried on.

9.3 Preparation for decontamination

Before the following reprocessing steps can be carried out, the devices must be disassembled as follows, or forwarded on for the subsequent reprocessing steps in open condition.
The torque ratchet can be disassembled for cleaning without the need for any tools. Fully unscrew the screw. The entire pawl can then be removed, followed by the optional flexible rod attachment.



It should be ensured that no areas are missed. The devices must be reprocessed in suitable screen baskets or drainage bowls (choose a size that is appropriate for the device). Minimum spacing specifications must be observed when fixing the devices in place inside the cleaning basket. Overlapping of the devices should be prevented in order to rule out damage to the devices as a result of the cleaning process.
When using several torque ratchets, do not interchange the individual parts. Each individual part belongs to the respective instrument.

9.4 Precleaning

Rinse the devices under cold municipal water of drinking-water quality (< 40°C) until all visible contamination has been removed. Hardened dirt should be removed using a soft brush or the accompanying cleaning pin. Cavities and lumens should be flushed out intensively (> 30 sec) with cold municipal water of drinking-water quality (< 40°C) using a water pressure gun (or similar device). Moving parts must be moved into their various positions.

9.5 Cleaning/disinfection

A) Manual cleaning process

1. Place the devices into an alkaline cleaning agent (0.5% *Neodisher® MediClean*) in an ultrasonic bath, for a period of 10 minutes and a frequency of 35 kHz. Do not exceed the max temperature of 40°C. The instructions of the cleaning agent manufacturer must be observed here.
2. Afterwards, completely clean the devices with a soft brush. If there are any cavities or lumens, flush these out intensively (> 30 sec) using a water pressure gun (or similar device).
3. Rinse the devices under running municipal water of drinking-water quality in order to remove the cleaning agent (> 15 sec).

Manual disinfection

1. Immerse the devices in a disinfectant listed by the German Association for Applied Hygiene (VAH) or the Robert Koch Institute (RKI). The instructions of the disinfectant manufacturer must be observed here. It must be ensured that the disinfectant can effectively reach all areas of the device (move the parts in the disinfectant bath and wash any concealed surfaces with disinfectant using a syringe (without cannula)).
2. The process is validated with the following disinfectant: 3% Korsolex plus, Bode Chemie Hamburg, 15 minutes.
3. Rinse the devices (wash off the insides, outsides and cavities completely) in demineralised water for > 60 sec.

Manual drying

Manual drying with a lint-free disposable towel. It is recommended that the cavities be blown out with sterile, oil-free compressed air, as this will largely prevent any water residues inside.
The device must never be heated to above 140°C.

B) Automatic cleaning/disinfecting process (RECOMMENDED)
(*washer, washer-disinfector*):

- 1-minute pre-cleaning with cold municipal water of drinking-water quality < 40°C
- Water drainage
- 3-minute pre-cleaning with cold municipal water of drinking-water quality < 40°C
- Water drainage
- 10-minute cleaning at 55°C±5°C with 0.2% alkaline cleaning agent (*0.2% Neodisher® MediClean*)
- Water drainage
- 1-minute rinsing with demineralised water < 40°C
- Water drainage
- 2-minute rinsing with demineralised water < 40°C

The specific instructions of the automated cleaning device manufacturer must be observed.

Automatic disinfection

Automatic thermal disinfection in a washer-disinfector, taking into account the national requirements with regard to the A0 value; e.g. A0 value 3000:
> 5 minutes at 92°C±2°C with demineralised water.

Automatic drying

Automatic drying in accordance with the washer-disinfector's automatic drying procedure for at least 30 minutes (at 60°C±5°C in the washing compartment). Any subsequent manual drying should be performed with a lint-free cloth, and the lumens blown out with sterile, oil-free compressed air.

Before sterilisation:

- **Areas highlighted with this symbol must be lightly moistened with handpiece oil using a syringe or needle. Then assemble the ratchet and carry out a function test.**

9.6 Sterilisation

The devices are sterilised using a fractionated pre-vacuum method (in accordance with DIN EN ISO 17665-1), taking into account the relevant national requirements. The devices must be sterilised in suitable sterilisation packaging.
Sterilisation must be performed using a fractionated pre-vacuum method with the following parameters:
132°C/270°F
≥ 3 minutes hold time
3 pre-vacuum cycles
Drying within a vacuum for at least 20 minutes

Flash sterilisation is not suitable for devices with lumens!
The autoclave manufacturer's instructions for use and the recommended guidelines for maximum loading with sterilisation items must be observed.
The autoclave must be installed, maintained, validated and calibrated in accordance with the regulations.

Additional information

The person carrying out reprocessing is responsible for ensuring that reprocessing is carried out in the reprocessing facilities with the appropriate equipment, materials and personnel in order to achieve the required results. The procedure and equipment used will therefore usually need to be validated and subjected to routine monitoring.

10 Function test

After reprocessing and before sterilisation, check the devices for the following:

- • Cleanliness
- • Damage, such as signs of corrosion (rust, pitting), discolouration, deep scratches, flaking, tears and wear.
- • Proper functioning, including the flexibility of flexible products
- • Devices that are not properly functioning or that are defective or excessively worn

Check devices for perfect surface qualities and functioning. Do not use any seriously damaged devices, devices with illegible markings or devices with signs of corrosion.

11 Servicing and repair

Servicing and repair

Do not carry out any repairs or modifications to the device independently. This work is the sole responsibility of authorised personnel appointed by the manufacturer, and must only be carried out by these individuals. If you have any complaints, grievances or feedback about our devices, please get in touch with us.

Return transport

Defective or non-compliant devices must have gone through the entire reprocessing procedure before being returned for repair/servicing.

12 Packaging, warehousing and disposal

Standard-compliant packaging of the devices for sterilisation in accordance with ISO 11607 and EN 868.
Store sterile devices in a dry, clean and dust-free environment at moderate temperatures, and so that they are protected against damage.
The manufacturer's medical devices should be stored in individual packagings, boxes or protective containers. Please take the utmost care when handling devices during transportation, storage and reprocessing. The user or designated specialist personnel are responsible for ensuring that the sterile condition is maintained following the sterilisation procedure.
The devices, packaging materials and accessories must be disposed of in accordance with the nationally applicable laws and regulations. No specific instructions are provided by the manufacturer in this regard.

13 Calibration/inspection

We recommend that the ratchet be calibrated/inspected once a year. The ratchet must have gone through the entire reprocessing procedure prior to dispatch.

14 Manufacturer

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15 Description of symbols used

REF	Order number (item reference)
LOT	Batch code
QTY	Order quantity
	Consult instructions for use
CE	CE mark
	Please note ("Please note: consult the accompanying documents")
	Symbol for "manufacturer"
	Non-sterile