EN - Universal Torque Ratchet with Bending Rod - Instruction Manual

REF **Ratchet N° 1-1000900, 1000901, 1000902, 1-1000900-G, 1000901-G, 1000902-G (10-50 Ncm)**

NON STERILE CE

Important note

Carefully read through these instructions before each use and store them somewhere that is easy for the user and/or for the relevant qualified personnel to access.

Carefully read the warning information indicated by this warning symbol. Improper use of the products can lead to serious injury to the patient, user or any third parties.

1 Purpose

1.1 Purpose / Indication

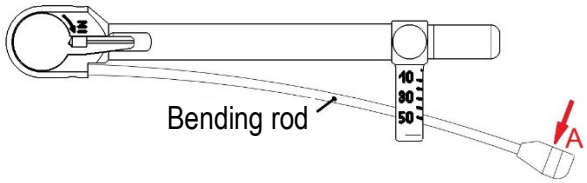
Ratchet for screwing in and unscrewing screws and implants with defined torque in the dental area. The torque ratchet may only be used by trained dental specialists.

1.2 Contraindications

For the torque ratchets, special contraindications can only be seen in connection with the total surgery procedure.

2 Handling

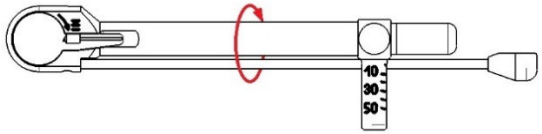
Prosthodontic setting – torque function: Used with the bending rod. The torque is indicated on the scale by the bending rod.



Apply pressure to component A in the direction of the arrow.
The desired torque is achieved when the centre of the bending rod coincides with the corresponding scale line. **ATTENTION:** The reading must always be done viewing directly from above.
Relieve the bending rod when the desired torque is reached. The bending rod springs back to its initial position.
ATTENTION: The ratchet must not be loaded above 50Ncm.

3 Changing direction of rotation

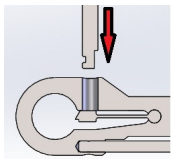
To change the direction of rotation, the ratchet must be rotated 180°. The label OUT should now be readable.



4 Replacing tools / inserts / ratchet wheels

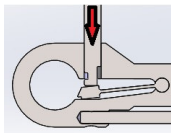
All you need as an aid is a tool with an elbow shank in accordance with DIN EN ISO 1797-1 or a tool with shank Ø =2,35mm.

Step 1.)



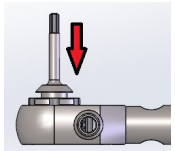
Insert tool with elbow shank or shank Ø =2,35mm by the cross hole.

Step 2.)



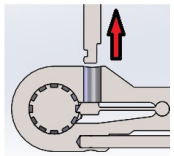
Lever out the bending pawl downward until you have completed step 3.).

Step 3.)



Insert the desired insert into the ratchet until it stops.

Step 4.)



Remove tool with elbow shank or shank Ø =2,35mm by the cross hole.

5 Materials

The torque ratchet with bending rod is made of stainless steels (1.4305, 1.4307, 1.4310).

6 Precautions and warnings

Attention!

The torque ratchet with bending rod is designed for dental use only and must not be used for any other purpose. Improper handling and maintenance as well as non-intended use can lead to premature wear of the approximator.

Material intolerance.

The medical devices must not be used if the user or healthcare professional knows that the patient doesn't tolerate certain materials.

Functional impairment

When coming into contact with aggressive substances, surgical instruments can corrode and their function may be impaired. For this reason, the preparation and sterilization instructions must absolutely be followed.

Operation conditions

To ensure the safe operation of the above products, proper maintenance and care of the products is essential. In addition, a functional or visual check should be carried out before each application. To do this, refer to the corresponding sections in these instructions for use.

Storage

There are no specific requirements for the storage of the products. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

7 Sterility

NON STERILE

The medical devices are not delivered in a sterile state and must be prepared and sterilised by the user according to the following instructions before the first and before any subsequent use.

8 Product life

When the torque to be set has been reached 5000 times, the lifetime ends.
Since the medical products of Josef Ganter Feinmechanik GmbH are manufactured from durable and long-term proven materials in the field of medical technology, it is not possible to define an exact lifetime. The product lifetime depends on wear and frequency of use. Please refer to the relevant notes on functional test before use.

9 Preparation

Warnings

- Frequent preparations impair the quality of the products.
- The water to be used must be of drinking water quality.
- In these preparation instructions, the cleaning and disinfecting agents used for the validation will be specified. If an alternative cleaning agent and disinfectant (RKI or VAH listed) is used, the responsibility lies with the conditioner.

9.1 Place of use

The first steps in preparing a product correctly start already in the surgical room.
Wherever possible, coarse impurities, residues of fillings, disinfection agents and other medicinal products should be removed before laying down the instruments.
Dry removal (humidified, closed system) is to be preferred wherever possible. Drying of residues must be avoided!
Long waiting periods before the preparation, e.g. overnight or over the weekend, are to be avoided with both types of removal (<6 hours).

9.2 Transport

The products must be disposed of dry immediately after use. This means that the products should be transported wet in a closed container from the place of use to the place of preparation so that the products do not dry.

9.3 Preparation for decontamination

The products are to be, insofar as possible, disassembled before the following preparation steps and the further preparation steps are to be carried out when they are open. Drying of residues must be avoided! The products must be prepared in suitable sieve baskets or drainage bowls (choose the size depending on the product). A minimum distance should be maintained between the products in the cleaning basket. Overlapping is to be avoided to prevent any damage to the product during the cleaning process.

9.4 Pre-cleaning

Rinse the products under cold municipal water of drinking water quality (<40°C) until all visible contamination has been removed. Any dirt still adhering to the product must be removed with a soft brush and/or the cleaning pin supplied. Hollow spaces and lumens must be intensively (>30 sec) rinsed out using a water pistol (or similar) with cold municipal water of drinking water quality (<40°C). Moving parts must be moved whilst they are being cleaned.

9.5 Cleaning / disinfection

A) Manual cleaning process

1. Place products in an alkaline cleaning agent (0.5% *Neodisher® MediClean*) in an ultrasonic bath for approx. 10 min. and with a frequency of 35 kHz. Do not exceed the maximum temperature of 40°C. Here, the instructions provided by the cleaning agent manufacturer must be followed.
2. Thoroughly clean the product with a soft brush afterwards. If there are any hollow spaces and lumens, intensively (>30 sec.) rinse them out using a water pistol (or similar).
3. Rinse the product under running municipal water of drinking water quality to remove the cleaning agent (>15 sec.).

Manual disinfection

1. Immerse the product in an *RKI*- or *VAH*-listed disinfecting agent. Here, the instructions provided by the disinfecting agent manufacturer must be followed. It must be ensured that the disinfecting agent really reaches all areas of the product (move the parts around in the disinfection bath and, if necessary, rinse hidden areas using a syringe – without a cannula – with the disinfecting agent).
2. The process is validated with the following disinfectant: 3% Korsolex plus (Bode Chemie, Hamburg) 15 minutes.
3. Rinsing of the products (cpl. rinsing of the inside, outside and hollow spaces) in demineralised water for >60 sec.

Manual drying
Dry manually with a lint-free, single-use cloth. To avoid leaving any water in hollow spaces, it is recommended that you blow these out with sterile, oil-free pressurised air.
The product must never be heated to over 140°C.

B) Automatic cleaning/disinfection process (RECOMMENDED)
(washing machine, RDG):

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

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

Automatic disinfection
Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the A0 value; e.g. A0 value 3000:
>5 minutes at 92±2°C
with demineralised 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 needed, manual subsequent drying using a lint-free cloth and blow-out the lumens with sterile, oil-free pressurised air.

9.6 Sterilisation

Sterilization of the products by means of fractionated pre-vacuum process (acc. to DIN EN ISO 17665-1), taking into account the respective national requirements. The sterilisation of the products must be done in suitable sterilisation packaging.
The sterilization shall be performed with a fractionated pre-vacuum method using the following parameters:
132°C / 270°F,
≥3 minutes retention time,
3 pre-vacuum cycles
Drying in vacuum for at least 20 minutes

Flash sterilization is not suitable for products with lumens!
The instructions for use of the autoclave manufacturer and the recommended guidelines for maximum loading with instruments to be sterilised must be observed. The autoclave must be properly installed, maintained, validated and calibrated.

Additional information
The preparator is responsible for achieving the desired results when actually performing the preparation in the preparation facility with the equipment, material and persons used. Therefore, as a general rule, the validation and routine monitoring of the procedure and the equipment used is required.

10 Functional test

Check products after preparation and before sterilisation with regard to the following aspects:

- • Cleanliness
- - Damage, including but not limited to signs of corrosion (rust, pitting), discoloration, deep scratches, flaking, cracking and wear.
- - Proper function, including flexibility of flexible products
- - Products not functioning properly or defective and excessively worn out

Check products for flawless surfaces and functionality. Do not use severely damaged products, products with unrecognisable markings or signs of corrosion.

11 Service Repair

Service and repair
Do not carry out any repairs or modifications to the product yourself. Only authorized personnel of the manufacturer is responsible and intended to do this. Should you have any complaints or remarks regarding our products, please do not hesitate to contact us.

Return
Defective or non-compliant products must have undergone the entire reprocessing process before being returned for repair/service.

12 Conditioning, storage and disposal

Standardized packaging of products for sterilization according to ISO 11607 and EN 868.
Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures.
The manufacturer's medical devices should be stored in individual packages, boxes or protective containers. Please handle the instruments with the utmost care during transport, storage and preparation. The user or the designated specialist personnel must ensure that the sterile condition is maintained after the sterilisation process.
The products, packaging material and accessories must be disposed of in accordance with national regulations and laws. The manufacturer does not provide specific instructions for this.

13 Calibration / Verification

We recommend to realise an annual calibration / inspection of the ratchet. The ratchet must have undergone the entire reprocessing process before shipping.

14 Manufacturer

Josef Ganter Feinmechanik, Niedereschacher Strasse 24, 78083 Dauchingen, Germany
Tel. (049)-(0)7720/4474, Fax (049)-(0)7720/61264 www.josefganter.de - info@josefganter.de

15 Description of the symbols used

REF	Order number (article reference)
LOT	Batch designation
QTY	Ordered quantity
	Observe user instructions
CE	CE marking
	Attention ("Attention, please note accompanying documents")
	"Manufacturer" symbol
	Non-sterile