CE

User instructions
ICX - ratchet

JOSEF GANTER Feinmechanik

FB-EV 048 GA universal torque ratchets EN (Version: 24/04/2018)

Thank you for choosing to buy one of our dental products.

Carefully read through these instructions before each use and store them somewhere that is easy for the user and 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.
To ensure that the condition and functionality is faultless for the intended use, the specifications of the following instructions must be complied with. Please be aware that handling implements improperly can negatively affect their service life and safety.

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.

1 Delivered condition, storage of brand-new products

As a general rule, the devices should be stored in a dry place and protected against dust, chemical fumes or components.
The products are delivered without tension at approx. 10 Ncm. This must also be maintained as the general storage condition to ensure optimum functionality and a longer service life.

2 Product details

This user manual is only applicable for the products specified below.

Product description / product group:
ICX - ratchet

	Catalogue and order number
REF	960001

Each individual part only belongs to the delivered implement. Exchanging components is not permissible (even with identical implements) and requires a new inspection to be performed by the manufacturer before the torque function can be used.

This product is a medical device and is only intended for use by trained dental specialists.
The relevant employee must be sufficiently qualified in accordance with statutory regulations, and with the training and hygiene requirements, for the repreparation of the device.
It's the user's responsibility to select suitable procedures and employees relating to the product.

2.1 Intended use

This torque ratchet is to be used for the temporary insertion and removal of screws and for the insertion of implants, as well as for loosening them in defined torque ranges for dental applications in the fields of implantology, osteosynthesis, surgery and prosthetics. The torque function can also be "blocked". In the blocked position, higher torques can be used for insertion, as well as removal.

For implements with ranges up to 80 Ncm → Using with loads above 100 Ncm can damage the implement.
For implements with ranges up to 100 Ncm → Using with loads above 120 Ncm can damage the implement.

2.2 Contraindication

Special contraindications can only be seen in connection with operation procedures. Therefore, the user is responsible for the selection of suitable methods and settings in accordance with the individual anatomical characteristics of their patients.

2.3 Combination with tools or other products

There are adaptors available which allow you to use this torque ratchet with many different tools. Adaptors manufactured by Josef Ganter GmbH are generally suitable. The user must ensure that they choose the suitable size for the intended tool connection.
Due to the large number of possible combinations (including combinations with the end tools of other manufacturers), there are always detailed technical specifications available under www.josefganter.de in the download area of the current catalogues.

When using adaptors produced by other manufacturers, their guidelines regarding the compatibility of said adaptors with these user instructions, at least with regards to the connection size to be used, the intended user and the repreparation, is to be checked. We are not liable for any damage caused by combinations with third-party products, unless the problem concerns a manufacturer that was expressly named in one of the catalogues mentioned in this paragraph.

3 Use / handling

Immediately before each use, the product must be checked for any possible signs of wear, loss or limitation of function or corrosion. In addition, the implement must be assembled correctly.
Damaged products or products with any of the aforementioned faults must be immediately scrapped and must not be used in this condition!

If the sterile packaging of products (after being prepared by the user) is damaged, the products should not be used and must undergo another repreparation according to these instructions.

3.1 Possible default settings

Prosthodontic setting – torque function: The desired torque range can be continuously set via the spring using the adjusting nut. The setting can be seen on the scale of the scale sleeve.

Surgery setting – blocked function: Turn the adjusting nut to the scale mark ∞ (infinity symbol). Do not tighten excessively.

(see ***Figure 1***) Do not loosen either of the screws X on the adjusting nut, as this leads to a loss of the factory default settings.

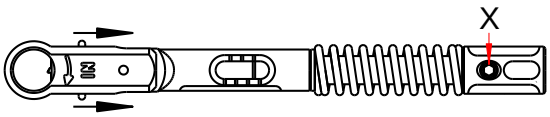

Figure 1

3.2 Change tool (adaptor)

Pull out the pin in the direction of the arrow (⟶) on both sides using your thumb and index finger and remove or insert the tool (adaptor) (see ***Figure 1***)

3.3 Correct handling of the torque release

- The pressure point for accurate torque release is only on the handle of the adjusting nut (see arrow in ***Figure 2***).
- Release by the press of a finger.
- Do not touch the handle with thumb and index finger to release.
- When the set torque is reached the scale sleeve snaps around the axis in the ratchet head. The release can be heard and felt.

Do not continue to press after the torque is released. The ratchet or dental components could be damaged.

When the handle is released, the ratchet returns to its original position.

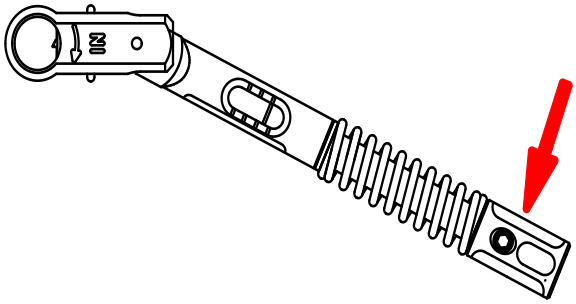

Figure 2

4 Material

The product is made from the following materials:
High-grade stainless steel
PEEK

5 (Re-)preparation

The torque ratchets will be delivered by Josef Ganter GmbH in a pre-defined state of cleanliness. They are optimally adjusted to the further handling by the end user described here. The work methods required will be validated by the manufacturer. In order to provide the user with information about a well-functioning procedure for the individual cleaning steps, an efficiency check of the repreparation for each determined procedure will be carried out in an accredited laboratory. The validation of the procedures used for cleaning and sterilisation is the responsibility of the user themselves, and must be done on-site, or it is the responsibility of a Central Sterile Supply Department (CSSD).

Each modification to the packaging or product also constitutes a modification to the validated delivery condition.
When using more than one torque ratchet, do not swap the individual parts. The individual parts each belong to a particular implement.
Do not use metal brushes or cleansing sponges.

- The preparation may only be performed by adequately qualified persons.
- The water used must be *at least* of drinking water quality. (see specifications in the individual preparation steps).
- In these preparation instructions, the cleaning and disinfecting agent used will be specified on the efficiency certificate. If you use an alternative cleaning and / or disinfecting agent, it must be listed by the *RKI* [Robert Koch Institute] or the *VAH* [German Association for Applied Hygiene] and must be compatible with the materials.
- 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.

Demineralised water should always be preferred when selecting a water quality for handling implements so that the corrosion-causing accumulation of salts and silicates can be avoided or reduced to an absolute minimum.

5.1 Transport / site of use – preparation

The first step in preparing a product correctly starts immediately after it has been used on a patient.
Heavy contamination, residues of fillings, disinfection agents and other medicinal products should be removed before the implement is stored away.

- Dry removal (humidified, closed system) is to be preferred whenever and wherever possible.
- As a general rule, surface drying of certain residues which are left after use is to 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).

5.2 Cleaning and disinfection

Cleaning and disinfectant solutions with a pH value between 4.5 and 10 are to be used for cleaning – follow the manufacturer's instructions for these products (e.g. purpose, dosage, exposure time, etc.)

As a general rule, when storing parts for cleaning, care must be taken to ensure that they touch or lie on each other as little as possible to avoid any areas being missed and so that the cleaning procedure can be performed as efficiently as possible.

5.2.1 Basics

For the cleaning and disinfection, a mechanised process should be used where possible (cleaning and disinfection unit). A manual process – even using an ultrasonic bath – should only be used if there is no option of a mechanised process, as it is significantly less effective and reproducible.

The preparation and pre-treatment described below must be carried out in both cases.

5.2.2 Preparation for decontamination

Heavy contamination must be removed from the implements directly after use (within 2 hours maximum).

Before being cleaned (regardless of the selected cleaning method), the torque ratchet must be disassembled into its individual parts. This can be done without tools. Only the adjusting nut must be completely removed. (see ***Figure* 3**)
Do not lose the plastic disc during this process, as this will impair the precision of the implement. (The plastic disc only needs to be removed if there is visible contamination. The disc can be removed *if needed.* Push the disc back in after cleaning.)

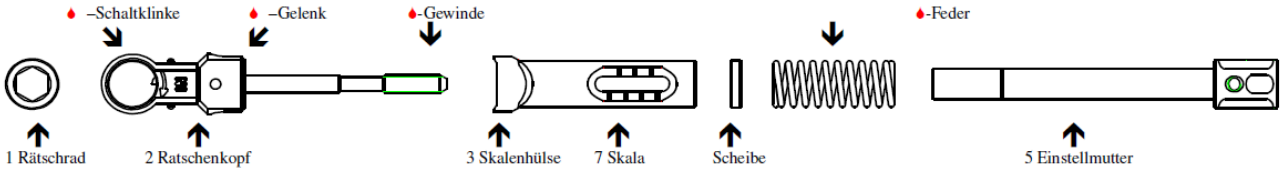

Figure 3

5.2.3 Pre-treatment

5.2.3.1 Pre-treatment process

Pre-cleaning must always be performed regardless of the following cleaning method. Rinse the products under cold municipal water (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. Hollow spaces and lumens must be intensively (>30 seconds) rinsed out using a water pistol (or similar) with cold municipal water (drinking water quality <40°C).

5.2.4 Mechanical process – thermal disinfection

Evidence of the fundamental suitability of the implements for an effective mechanical cleaning and disinfection was provided by an independent and accredited testing laboratory that is recognised by the ZLG [Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices] *(§15 (5) MGP* [Medical Products Directive]*) under use of the Miele G7835 CD cleaning and disinfection unit (thermal disinfection, Miele & Cie. KG, Gütersloh) and the pre-cleaning and cleaning agents neodisher ® mediClean (Dr. Weigert GmbH & Co. KG, Hamburg). For this, the procedure described above was used.*

5.2.4.1 Cleaning and disinfection unit and media

When choosing a cleaning and disinfection unit, it should be ensured:

- that the effectiveness of the unit has been verified (e.g. *DGHM* [German Association for Hygiene and Microbiology] or *FDA* [Food and Drug Administration] approval / clearance / registration or CE label in accordance with DIN EN ISO 15883),
- that where possible a tested thermal disinfection programme (A_0 value > 3000 or – with older devices – at least 5 minutes at 90°C / 194°F) is used (with chemical disinfection there is a risk of disinfecting agent residue on the implements),
- that the programme used is suitable for the implements and has enough flush cycles,
- that only demineralised water is used for rinsing,
- that the air used to dry has been filtered (oil-free, low-microbiological contamination and particle-free) and,
- that the cleaning and disinfection unit is regularly serviced and tested.

The materials, concentrations, temperatures and treatment times, as well as rinsing requirements, specified by the cleaning and disinfection agent manufacturer must be adhered to at all times.

5.2.4.2 Mechanical cleaning / disinfection (→ RECOMMENDED)

Programme parameters used during certification (Programme: Des-Var-TD / Miele G7835 CD cleaning and disinfection unit):

- The parts were placed on a tray and put in the mobile injection unit (E450/1)
- 1 minute pre-cleaning (cold municipal water, drinking water quality <40°C) → Drain water → 3 minutes pre-cleaning (cold municipal water, drinking water quality <40°C) → Drain water
- 10 minutes cleaning at 55±5°C with 0.2% alkaline cleaning agent (0.2% Neodisher® MediClean) → Drain water
- 1 minute rinsing with demineralised water <40°C → Drain water → 2 minutes rinsing with demineralised water <40°C → Drain water
- Automatic disinfection > 5 minutes at 92±2°C with demineralised water.
- Automatic drying process 90±2°C of the cleaning and disinfecting unit for at least 30 minutes (≙ 60±5°C in the washing compartment).

(Re-)preparation process:

- Place the implements in the cleaning and disinfection unit. Make sure that the implements are not touching each other.
- Start the programme.
- When the programme ends, immediately remove the implements from the cleaning and disinfecting unit and ensure that they are dry enough before packaging.
- Inspect and package the implements as soon as possible after removing them from the unit.

5.2.4.3 Manual subsequent drying

If a manual subsequent drying is required, do so with a lint-free cloth and / or blow-out the lumens with sterile, oil-free pressurised air.

5.2.5 Manual process

Evidence of the fundamental suitability of the implements for an effective manual cleaning and disinfection was provided by an independent, accredited and ZLG-recognised (§15 (5) MGP) testing laboratory under use of the cleaning and disinfection agents named below. For this, the procedure described above was used.

5.2.5.1 Manual cleaning

1. Place products in an alkaline cleaning agent (0.5% Neodisher ® MediClean) in an ultrasonic bath for approx. 10 minutes. 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 seconds) rinse them out using a water pistol (or similar).

3. Rinse the product under running municipal water (drinking water quality) to remove the cleaning agent (>15 seconds).

5.2.5.2 *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 efficiency verification for the process was done using the disinfecting agent: 3% Korsolex plus (Bode Chemie, Hamburg) 15 minutes.
3. Rinse the products (complete rinsing of the inside, outside and hollow spaces) in demineralised water for >60 seconds.

5.2.5.3 *Manual drying*

1. 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.

5.3 Check

Careful inspections and function tests before and after use are the best way to identify an implement which is no longer functional and to separate it off. Particular attention must be paid to the working and function areas (e.g. the adapter fixture and torque release) and also to moving parts during the inspection.
Let the parts cool down to room temperature. Parts with damaged surfaces, chips, dirt, discolouration and corrosion must be separated off. Separate off any deformed, worn out (with regards to their function) or otherwise damaged implements.
Implements which are still dirty must be cleaned and sterilised again.

5.4 Maintenance

When using more than one torque ratchet, do not swap the individual parts. The individual parts each belong to a particular implement.

Lightly grease areas marked with ♦ (see ***Figure 3***) with implement care oil.

Here, care must be taken to ensure that only implement oils (paraffinic white oil, without corrosion inhibitors or any other additions) which – taking into consideration the maximum sterilisation temperature which can be used – are approved for steam sterilisation and have a tested biocompatibility are used, and that they are only used in the smallest amounts possible.

Assemble the ratchet and perform a functionality test.

The torque ratchet must be without tension at max. 10 Ncm after being assembled and before being sterilised.

5.5 Packaging

The sterilisation of the products must be done in suitable sterilisation packaging. The manufacturer's verification was done using doubled sterilisation packaging (hospital standard); that means that the single suitable sterilised foil packaging can also be used.

Flash sterilisation and the sterilisation of unpackaged implements is absolutely prohibited!

5.6 Sterilisation

Evidence of the fundamental suitability of the implements for an effective sterilisation was provided by an independent, accredited and ZLG-recognised (§15 (5) MGP) testing laboratory under use of an EHS3870 pre- and post-vacuum autoclave (Tuttnauer Europe B.V., Breda) and RB 51-3P and RB52-3P sterilisation packaging (Steriking-foil). For this, the procedure described above was used.
3 vacuum cycles | 132°C / 270°F | ≥ 1.5 minutes stop time | Drying in the vacuum for at least 20 minutes[3]

5.6.1 Sterilisation process – fractionated vacuum procedure

Only the specified sterilisation procedures may be used for sterilisation.
Other sterilisation procedures are not permitted and their efficiency must be certified by the user / processor themselves.

- **Fractionated vacuum procedure** [1;2] **(with sufficient product drying**[3]**)**
- Steam steriliser conforming to DIN EN 13060/DIN EN 285 and ANSI AAMI ST 79 (FDA clearance in the USA)
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance evaluation (PQ))
- Maximum sterilisation temperature 134°C (273°F) including the tolerance margin in accordance with DIN EN ISO 17665
- Sterilisation time (time exposed to the sterilisation temperature)

6 Storage

After the sterilisation, the products must be stored dust-free and dry in the sterilisation packaging.

7 Material resistance

When selecting the cleaning and disinfecting agents, please ensure that they do not contain the following elements:

- Organic, mineral and oxidising acids or strong alkaline solutions
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidising agents (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic / halogenated hydrocarbons

Acidic rinsing agents or neutralising agents should not be used!
All implements should not be subject to temperatures above 138°C (280°F).

[1] At least 3 vacuum stages
[2] The less effective gravitation procedure may only be used if the fractioned vacuum procedure is not available as an option, as it requires significantly longer sterilisation periods which must be determined and validated under the responsibility of the user, and specifically for their implements, devices, procedures and parameters.
[3] The actual required product drying time depends directly on the parameters, which are solely the responsibility of the user (loading configuration and density, sterilisation status,...) and must therefore be determined by them. As a general rule, drying times should not be less than 20 minutes.

8 Product life

Usually, frequent repreparing has little effect on these implements – if sufficient care is taken, and as long as the implement is undamaged and fully functioning. The end of the product's service life is normally determined by wear and damage caused during use and depends on many factors – including the type, duration and frequency of application, as well as the handling storage and transportation of the implements. Damaged, blunt or contaminated implements should not be used.
Josef Ganter GmbH is not liable for any damage or injury caused by misuse. The same applies for any damage, such as disproportionate mechanical effects, crashes, overloading, etc., caused by improper repreparation or handling.

9 Repairs / maintenance

In delivered condition, the factory settings have an accuracy of ± 10% with regards to the adjustable torque value.
Josef Ganter GmbH offers a repair and inspection service for torque ratchets.

We recommend an annual inspection of the torque ratchet by the manufacturer.
If the implements are repaired by companies or persons which are not expressly authorised to do so by Josef Ganter GmbH, all guarantees shall become null and void.

The implement must be visibly cleaned and sterilised according to these guidelines before being dispatched (e.g. by using a cover indicator on sealed sterilised foil). Otherwise, the product will be returned to the sender at their expense and without further processing.

10 Disposal

If the implements can no longer be repaired or prepared, they should be disposed of according to the general waste management of practice or clinic waste. Regional regulations must be observed for the disposal.

11 Additional information

Additional jointly applicable requirements for the preparation of medical products can be found under www.rki.de or www.a-k-i.org

12 Information about the symbols used and the manufacturer

Symbols used

Symbol	Description / symbol for ...
	... Manufacturer
REF	... Article number
LOT	... Batch code
	... Observe user instructions
CE	... CE compliance
NON STERILE	... Non-sterile
	... Warning

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