Instruction for use
Torque wrench
(TW50)

Application

Torque ratchet for inserting and removing dental screws with a defined torque. The torque function can also be “blocked”; the blocked position enables greater torque to be transferred when placing implants, and allows connections to be loosened.

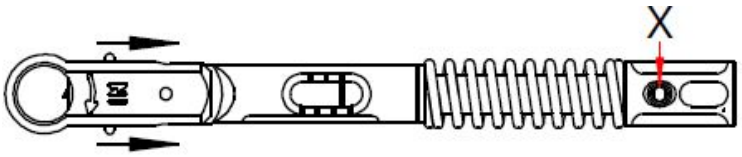
The torque ratchet may only be used by trained dental specialists.

Handling

Prosthodontic setting − torque function: The desired torque can be continuously set via the spring using the adjusting nut. The scale on the scale sleeve shows the setting.

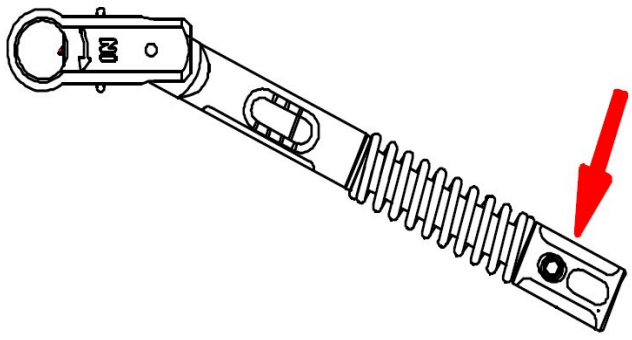
Surgery setting − blocked function: Turn adjusting nut to scale mark ∞ (infinite). Do not tighten excessively. Store without tension at 10 Ncm.

Caution! The ratchet must not be subjected to stress above 100 Ncm. Do not loosen the two adjusting nut screws (X), as this leads to a loss of calibration.



Exchanging tools

Using thumb and index finger, pull the post back on both sides in the direction of the arrow and remove or insert tool.



Correct handling of torque release

The pressure point for accurate torque release is located exclusively on the handle of the adjusting nut (see arrow). Release by pressing with finger only. 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 the starting position.

Reprocessing:

The reprocessing cycle is prepared according to the manufacturer's instruction.

Preparation
Treatment instructions/warnings

To avoid damage, do not use metal brushes or cleaning sponges.

Only use cleaning and disinfectant solutions with a pH value of between 4.5 and 10. Follow the manufacturer's instructions (e.g., intended purpose, dosage, exposure period and replacement of the solution).

The ratchet is not sterile when delivered and must be cleaned and sterilised before it is used.

When using several torque ratchets, do not interchange the individual parts. Each individual part belongs to the respective instrument.

Restriction regarding repreparation

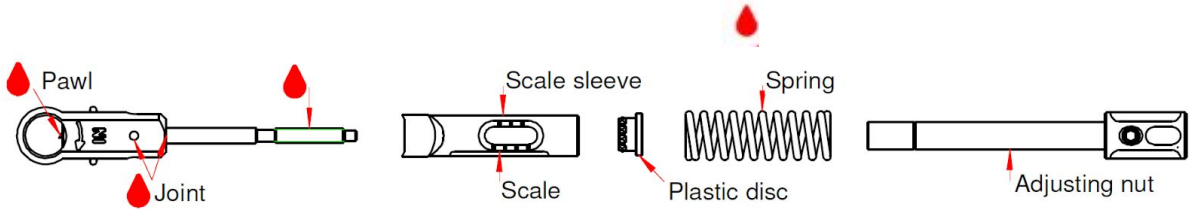
The end of the product's service life is normally determined by wear and damage caused during use and by incorrect handling.

Preparation for cleaning

The torque ratchet can be disassembled into its individual parts, without the need for tools, by completely unscrewing the adjusting nut.

Do not lose the plastic disc as this will impair the instrument's accuracy.

The plastic disc does not normally need to be removed. If necessary, the disc can be pulled out. After cleaning,reinsert the disc.



Clean the parts under cold running water using a soft brush to remove all visible soiling. Ensure that all openings and cavities are thoroughly rinsed. Do not allow blood and other soiling to dry on.

Cleaning and disinfection: Manual

Ultrasonic cleaning bath: Place the parts into a wire basket and ensure that the parts do not touch, in order to avoid acoustic shadows. Clean for 3 minutes in an ultrasonic cleaning bath (35-40 kHz) at a temperature of 40°-50°C with an enzymatic cleaning solution. Ensure that the parts are completely immersed in the water, without the formation of any bubbles. Rinse with clear, cold water; if possible, use deionised water. Dry the parts with a lint-free cloth and blow dry with compressed air.

Cleaning and disinfection: Automatic, Cleaning and disinfection device:

Securely apply the cleaned ratchet parts to the carrier. Do not overload the carrier. Start the program. After rinsing, chemical cleaning starts at 40-60°C. Residues from the cleaning process must

be reliably removed in the subsequent rinsing phase. Avoid damage to the material from neutralising reagents. Thermal disinfection is achieved at 90-95°C. The subsequent treatment with deionised water is followed by adequate drying. Remove the ratchet parts from the device immediately after the program ends.

Maintenance, inspection and testing

Allow the parts to cool to room temperature and visually inspect them for residues of proteins and other soiling. If necessary, repeat the preparation steps.

Lightly lubricate the areas marked with  using contra-angle handpiece oil. Assemble ratchet and carry out functional test.

Sterilisation packaging

Place the ratchet into packaging suitable for sterilisation according to ISO 11607 and EN 868. The bag must be large enough for the instrument. Closures must not be under tension.

Sterilisation

Method: Fractionated pre-vacuum process in accordance with ISO 17665
Temperature: heating to 134°C, max. 137°C
Pressure: 3 pre-vacuum phases with a minimum pressure of 60 millibars
Holding period: 5 minutes
Drying time: at least 10 minutes
After sterilisation, inspect the sterile packaging for damage and check sterilisation indicators.

Storage

Store the ratchet without tension at 10 Ncm, at a moderate temperature, and in a dry, dust-free, well-ventilated place, in which there is no corrosive steam.

Calibration

Manufacturer recommend annual calibration of the ratchet. The ratchet must be cleaned and sterilised before shipping,otherwise the product will be returned to the manufacturer for calibration. For this purpose, please contact our TRATE Quality Department via our web page: www.trate.com

Further information

This medical product is CE marked in accordance with Directive 93/42/EEC on medical device.

Validity

Upon publication of these instructions for use (IFU), all previous versions are superseded.

Please note

For the purpose of legibility, TRATE does not use ™ or ® in the text. This does not affect TRATE's rights with regards to registered trademarks.

Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.

Signs explanation

	Consult instructions for use

REF	Catalogue number
LOT	Batch code
	Non-sterile
	Manufacturer
CE	CE compliance
	Warning

Contact details

Manufacturer	**Supplier**
Josef Ganter Feinmechanik GmbH, Niedereschacher Straße 24, DE-78083 Dauchingen Tel. +49 (07720) 60995-0 www.josefganter.de info@josefganter.de	TRATE AG Seestrasse, 58 8806 Bäch, Switzerland. www.trate.com, www.roott.ch e-mail: info@trate.com

Change history:

Ver	**Date**	**Change description**	**Responsible**
01	2018-07-12	Printing date	V. Shulezhko D. Karpavicius
02	2020-02-11	Revised according to the updated instruction of manufacturer 2020.01.24, rev.2. FB-EV 049GA_Drehmomentratsche _de_en_it_fr. There are no changes in use. Updated contacts of manufacturer. Removed not needed signs explanations: Use by, Sterilized using irradiation, Do not use if package is damaged, Do not reuse, Keep away from sunlight, Keep away from water. Added signs explanations: CE compliance, Warnings. The reprocessing cycle is prepared according to the manufacturer's instruction, marked with warning sign. Also warning signs marked in text in clauses „Handling" and „Preparation". As area needed to be lightly lubricated added „Spring" (symbol).	V. Shulezhko