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DSI Ratchet Wrench

INSTRUCTIONS FOR USE

INTENDED USE
These ratchets are to be used for the temporary insertion and removal of screws and for the insertion of implants, as well as for loosening their joints for dental applications in the fields of implantology, osteosynthesis, surgery and prosthetics.

⚠ – The use with loads exceeding 250 Ncm can damage the implement.

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.

COMBINATION WITH TOOLS OR OTHER PRODUCTS
There are adaptors available that allow you to use these ratchets with many different tools. The user must ensure that they choose the suitable size for the intended tool connection.

⚠ – 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.

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.

POSSIBLE DEFAULT SETTINGS
Surgery setting – ratchet function available but without torque function.

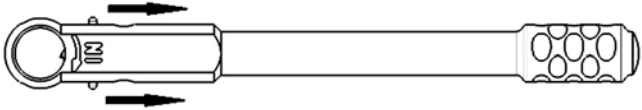

Figure 1

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).

CORRECT HANDLING
• The pressure point is only on the end of the handle (see arrow in Figure 2).

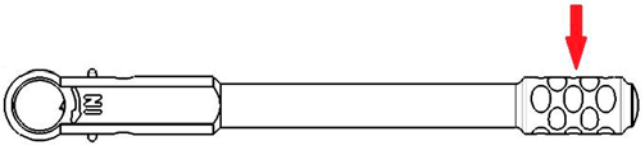

Figure 2

• Apply pressure in direction of arrow with only one finger. (see arrow in Figure 2).

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

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 must be removed before the implements are stored away.

Dry removal (humidified, closed system) is to be preferred whenever and wherever possible. For disposal, standard hospital regulations must be observed. The torque ratchet must be transported and disposed of in a closed container or tight protective cover.

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).

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.

PREPARATION FOR DECONTAMINATION

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

The ratchet must be disassembled into its individual parts before being cleaned (regardless of the selected cleaning method). This can be done without tools. The handle must be completely removed. (see Figure 3).

Make sure not to lose the spring during disassembly and cleaning. Furthermore, the tools and ratchet wheels must be removed from the ratchet head.

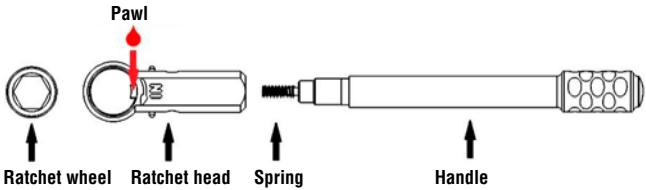

Figure 3

PROCEDURE / 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).

MANUAL CLEANING

1. Place products in an alkaline cleaning agent 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 afterward. 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).

MANUAL DISINFECTION

1. Immerse the product in the 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 for 15 minutes.
3. Rinse the products (complete rinsing of the inside, outside, and hollow spaces) in demineralized water for >60 seconds.

MANUAL DRYING

Dry manually with a lint-free, single-use cloth. To avoid leaving any water in hollow spaces, blow these out with sterile, oil-free pressurized air.

CHECK

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

MAINTENANCE

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 sterilization temperature which can be used – are approved for steam sterilization and have tested biocompatibility are used, and that they are only used in the smallest amounts possible.
Assemble the ratchet and perform a functionality test.

PACKAGING

The sterilization of the products must be done in suitable sterilization packaging. Flash sterilization and the sterilization of unpackaged implements are absolutely prohibited!

STORAGE

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

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).

PRODUCT LIFE

The product life ends if the set torque is reached 5000 times. Usually, frequent preparation 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.
Mechanically or visibly damaged, corroded or contaminated implements should not be used. Repreparation can be negatively affected due to surface defects of the implements. Josef Ganter GmbH is not liable for any damage or injury caused by misuse.
The same applies to any damage caused by improper repreparation or handling such as disproportionate mechanical impacts, falling down, mech. overload, etc.

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

STORAGE
As a general rule, the devices should be stored in a dry place and protected against dust, chemical fumes or components.
Service life is shortened by improper storage.

PRODUCT DETAILS
This user manual is only applicable for the products specified below.
Ratchets (Ref: SR)

MD – 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 require-ments, for the repreparation of the device.
It's the user's responsibility to select suitable procedures and employees relating to the product.

SYMBOLS

Catalogue number	REF	Consult instructions for use	
Batch Code	LOT	Caution	
Quantity	QTY	Non-sterile product	
Use by date		Magnetic resonance conditional	
Medical Device	MD	Manufacturer	

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.