Torque Wrench Tool

Instructions for Use

REF **133760 and 133761**

℞ ONLY

MD

For Sale in the U.S. and Canada

Caution: U.S. Federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

This IFU is only applicable for the products specified below.

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

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 approximately 10Ncm. This must also be maintained as the general storage condition to ensure optimum functionality and a longer service life.

PRODUCT DETAILS

	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.

INTENDED USE

MD	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.

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ARGEN®

For implements with ranges up to 80Ncm → Using with loads above 100Ncm can damage the implement. For implements with ranges up to 100Ncm → Using with loads above 120Ncm 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. The torque ratchet must not be used in case of any intolerance or allergies against conventional surgical stainless steels.

COMBINATION WITH TOOLS OR OTHER PRODUCTS

There are adaptors available which allow you to use this torque ratchet with many different tools. Adaptors sold by Argen are 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) please contact your distributor or check with our customer service department

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 our catalogues.

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

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.

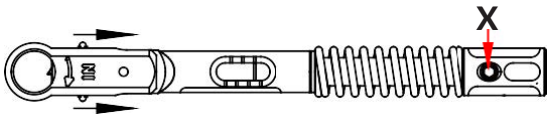

Figure 1

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 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.

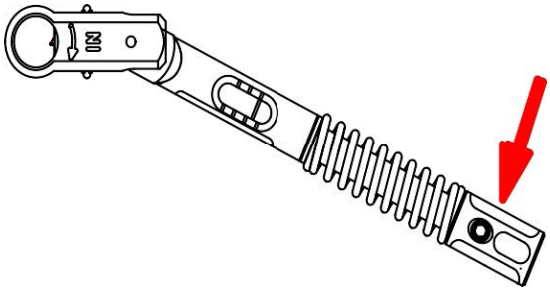

Figure 2

MATERIAL

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

(RE-)PREPARATION

The validation of the procedures used for cleaning and sterilization is the responsibility of the user themselves, and must be done on-site.

⚠	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 ph value must be between 4.5 and 10. • 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.

Demineralized 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.

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.

BASICS

For the cleaning and disinfection, a mechanized 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 mechanized process, as it is significantly less effective and reproducible.
The preparation and pre-treatment described below must be carried out in both cases.

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.)

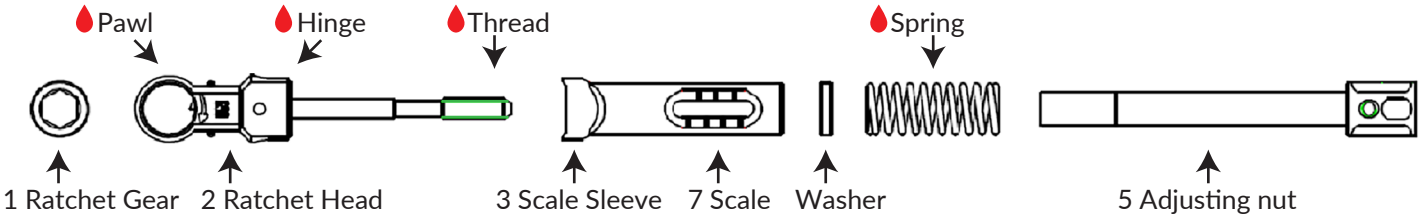

Figure 3

PRE-TREATMENT

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 dirt 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).

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 recognized by the ZLG [Central Authority of the Lander 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, Gutersloh) and the pre-cleaning and

cleaning agents Neodisher® MediClean (Dr. Weigert GmbH & Co. KG, Hamburg). For this, the procedure described above was used.

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 program (A0 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 program used is suitable for the implements and has enough flush cycles,
- that only demineralized 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.

Mechanical cleaning / disinfection (→ RECOMMENDED)

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

- The parts must be 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 demineralized water <40°C → Drain water → 2 minutes rinsing with demineralized water <40°C → Drain water
- Automatic disinfection > 5 minutes at 92±2°C with demineralized 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 program.
- When the program 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.

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 pressurized air.

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-recognized (§15 (5) MGP) testing laboratory under use of the cleaning and disinfection agents named below. For this, the procedure described above was used.

Manual cleaning

1. Place products in an alkaline cleaning agent (for example, 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).

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 demineralized water for >60 seconds.

Manual drying

1. 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 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, discoloration 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 sterilized again.

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 sterilization temperature which can be used – are approved for steam sterilization 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. 10Ncm after being assembled and before being sterilized.

PACKAGING

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

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

STERILIZATION

Evidence of the fundamental suitability of the implements for an effective sterilization was provided by an independent, accredited and ZLGrecognized (§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 sterilization packaging (Steriking-foil). For this, the procedure described above was used. These requirements must be complied with:
3 vacuum cycles | 132°C / 270°F | ≥ 1.5 minutes stop time | Drying in the vacuum for at least 20 minutes[3]

STERILIZATION PROCESS – FRACTIONATED VACUUM PROCEDURE

Only the specified sterilization procedures may be used for sterilization.
Other sterilization 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 sterilizer 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 sterilization temperature 134°C (273°F) including the tolerance margin in accordance with DIN EN ISO 17665
- Sterilization time (time exposed to the sterilization temperature)

STORAGE

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

MATERIAL RESISTANCE

When selecting the cleaning and disinfecting agents, please ensure that they do not contain the following elements:
- Organic, mineral and oxidizing acids or strong alkaline solutions
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic / halogenated hydrocarbons

Acidic rinsing agents or neutralizing 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 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 must not be used.
Argen 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.

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. Dispose of components and packaging in accordance with national, state, regional, or local regulations.

FURTHER INFORMATION

For additional information about the use of ArgenIS products, please contact:
(800) 255-5524 (Toll-free) or info@argen.com

SYMBOLS GLOSSARY

The following table describes the symbols that may be printed on the packaging label. Please refer to the packaging label for the applicable symbols related to the product.

Symbol	Title	Description
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Prescription use only per US FDA	Caution: Federal law restricts this device to sale by or on the order of a licensed dentist

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer
	Importer	Indicates the entity importing the medical device into the locale
	Medical device	Indicates the item is a medical device
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
QTY	Quantity	Indicates the quantity

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[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 sterilization 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, sterilization status,.) and must therefore be determined by them. As a general rule, drying times should not be less than 20 minutes.