



**GB: Torque wrench**

**1. PRODUCT IDENTIFICATION**

This user's instructions relate to the CRI5 torque wrench, recommended for carrying out surgical procedures and prosthesis protocols associated with dental implants made by Sweden & Martina S.p.A. Should the device be used in operations involving the implants of manufacturers other than Sweden & Martina S.p.A., the liability of Sweden & Martina S.p.A. will be limited and the product Warranty rendered void (see the later section "Liability for Defective Products and Terms of Warranty").

The torque wrench is sold along with the following accessories (fig. A):

- Gel lubricant
- Adjustment spanner to quickly obtain high torque values.

**2. DESCRIPTION AND USE**

The torque wrench has a dual function:

- Set spanner for screwing dental implants into the surgical sites during implant operations.
- Torque wrench able to release at a torque that can be reset, to be used for final tightening of the fixing screws for pillars that are part of the implant systems made by Sweden & Martina S.p.A.

This ratchet spanner can be disassembled, is multi-purpose, and is sold in a non sterile state. Before using it clean and sterilise the instrument each time, following these user's instructions. Adequate maintenance is essential for correct functioning of the device and to maintain its lifespan. For this reason, along with the device instructions are supplied that explain all the phases in detail, step by step, for disassembly and correct reassembly of the device during cleaning operations. The personnel that use this instrument must be specifically trained and have read the user's instructions before handling it in any way.

Once sterilised, the spanner is ready for use. A test to check correct assembly and functioning of the spanner is necessary before each operation, whether it be surgical or prosthetic.

To torque is adjusted by aligning the mark for the required torque, see the figure C. In particular:

- the "IN" arrow that can be seen on the head (fig.B-part.1) seen from above, indicates the position of the spanner for tightening.
- the "OUT" arrow that can be seen on the head (fig.B-part.1) seen from above, indicates the position of the spanner for unscrewing.
- An unlimited torque position is obtained by positioning the torque adjustment device (fig.B-part.5) at the notch marked "R" on the handle of the ratchet casing.

PLEASE NOTE: Adjusting the torque is always done by tightening the ring nut located at the bottom of the tool's handle. Should a torque be required that is lower than that in use, turn it at least two turns below the new torque required, and turn it up again to the torque required.

The kit includes an adjustment spanner that makes it possible to achieve high torques quickly and simply (fig.D).

Comment: Any deterioration of the tightening, inserting, and torque mechanisms must be checked by personnel responsible for using and maintaining this dental tool. The pieces of this tool cannot be interchanged and so it is not possible to take a piece from one spanner to replace that on another as each ratchet is calibrated INDIVIDUALLY. If a piece should be lost, please return the instrument to Sweden & Martina S.p.A. for the necessary repair of the same. No assembly component for the ratchet can be sold individually.

Non-observance of these directions could result in aesthetic problems and cause damage to the patient's health.

**3. INTENDED USE**

The torque wrench, with torque adjustment, is a dental device which allows the tightening and loosening of screws, prosthetic elements, and implants. The product must be used and handled exclusively by medical and dental staff having the necessary authorisation and professional preparation.

**4. MANUFACTURER'S DETAILS**

The manufacturer of CRI5 torque wrench which is the subject of these User's Instructions is:

**Sweden & Martina S.p.A.**  
Via Veneto 10 - 35020 Due Carrare (Padua) - Italy  
Tel. +39 049.91.24.300 - Fax + 39 049.91.24.290  
E-mail: info@sweden-martina.com - www.sweden-martina.com

**5. RAW MATERIALS USED**

The materials used for making the CRI5 torque wrench have been selected on the basis of the properties required for their intended use, in compliance with Regulation (EU) 2017/745.

The CRI5 torque wrench is made of surgical steel.

Patients must always be consulted in advance to ascertain if they are allergic to the use of steel.

**6. WARNINGS**

The torque wrench is sold in a NON-STERILE pack. Therefore, it must be cleaned, disinfected and sterilised before use, following the directions given below. Non-observance of this warning could cause the patient infections. We recommend collecting and keeping complete clinical, radiological and x-ray documentation on file.

The code, contents description and batch number are given on every package. This data must always be quoted by the dentist for any communication related to it.

The packaging complies with European standards.

Whenever handling the devices, both during their employment and when performing cleaning and sterilisation operations, we recommend always wearing surgical gloves for personal protection from bacterial contaminations.

**7. RECOMMENDATIONS:**

This instrument must not be used for applications other than those mentioned in this Instruction for Use or with equipment that affects the expected performance of the device.

The set torque must comply with the requirements defined by Sweden & Martina.

In the event of deterioration of the screwing or ratcheting mechanisms, the medical device must be inspected by the person responsible for use and maintenance of the device. In the event of a defect or change in device performance, return the wrench to Sweden & Martina.

During assembly, it is essential to not mix different components belonging to different instruments as the parts are not interchangeable.

If any part is misplaced, please return the instrument in question immediately to Sweden & Martina. No part may be sold separately.

Do not store the wrench with the spring compressed, but adjusted to the minimum torque.

This device must not be sterilised in its original packaging.

We recommend practicing the disassembly and reassembly operations, following the instructions mentioned here.

**8. HANDLING PROCESS**

The procedures described below must be carried out before initial use, and before every subsequent operation.

Failure to comply with these instructions may result in cross infection occurring.

**a. Disassembly of the torque wrench**

Disassemble the spanner completely as indicated in fig.E 1-3:

> Fig. E1: Unscrew the torque adjustment screw (fig.B part.5) completely and remove the spring housed in the handle of the ratchet casing. Do not separate the spring (fig.B part.6) from the pin that acts as a stop (fig.B part.7).

> Fig. E2: With the hexagonal point (fig.B part.4) at the base of the torque adjustment screw (fig.B part.5), unscrew and completely remove the lid fixing screw (fig.B part.10) from the side marked OUT. Exert a slight pressure to avoid damaging the hexagonal point.

> Fig. E3: Once you have removed the lid, remove the two components contained inside the ratchet head: The ratchet wheel (fig.B part.2) and pawl (fig.B part.3).

**b. Cleaning**

As soon as possible after each use of the wrench, place it in a container filled with a disinfectant/detergent solution and cover everything with a cloth. The purpose of this operation is to prevent the drying of contamination agents coming from the patient, to dissolve them, and subsequently to facilitate cleaning and make it more effective.

**c. Disinfecting**

Use an appropriate neutral cleaning solution, paying attention to the manufacturer's Instructions for Use. Still using the brush, apply the cleaning solution to the surfaces. Rinse with distilled water for at least 4 minutes. Make sure that the flow of water passes copiously through any holes.

For automated cleaning, using ultrasound: Use an ultrasound tank together with an appropriate cleaning solution. Exclusively neutral cleaning solutions should be used. The concentration of the solution and duration of the washing must be in observance of the manufacturer's instructions. Use demineralised water to prevent stains and haloes. During this cycle, avoid contact between the pieces as this causes deterioration of the machined surfaces, which results in a loss of precision of the torque measurement.

When emptying out, check the recesses of the devices, holes and so on, to ensure that all residues have been completely removed. If necessary, repeat the cycle or clean by hand.

Comment: Blood residue or other deposits reduce the effectiveness of sterilisation, that is why thorough cleaning is important. During all the cleaning cycles, avoid liquid spraying or splashing, and use adequate protection while working. Avoid contact between this tool and other nickel-plated instruments.

**d. Assembling the torque wrench**

Before proceeding with sterilisation, the pieces must be reassembled. Dry the pieces and lubricate the working areas moderately, then reassemble the spanner as indicated in fig. F 1-4 (excessive lubricant causes it to surface on the instrument again during sterilisation). Only use the "Instrument Lubricant" supplied.

> Fig.F.1: After lubricating the parts shown in the figure, insert the two elements that make up the ratchet head in the following sequence: The ratchet wheel (fig.B part.2) and then the pawl (fig.B part.3).

> Fig. F.2: Lubricate the contact area between the ratchet wheel (fig.B part.2) and the pin of the pawl (fig.B part.3).

> Fig. F.3: Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet casing, position the lid (fig.B part. 1) and turn the ratchet casing from the OUT side. Tighten the screw (fig.B part.10) using the hexagonal point on the torque adjustment screw (fig.B part. 4).

> Fig. F.4: Lubricate the spring inside the ratchet sleeve, as shown in the figure. Assemble the torque adjustment screw (fig.B part.5) checking that the instrument works correctly and activating the nut wheel manually.

This procedure is important in order to maintain the instrument's precision within a tolerance of  $\pm 10\%$  of maximum torque. Make the torque and insertion mechanism work to check that it is working properly. Remove any traces of lubricant from the external surface of the spanner. Put the device into suitable sterilisation bags.

**e. Sterilisation**

Before sterilisation, the wrench must be fully assembled and adjusted to its minimum torque.

The medical device must undergo steam sterilisation.

- Recommended cycle: 3 (4 for the US market) pre-vacuums, 18 minutes at 134°C / 273°F at 2 bars and drying for 20 minutes.

We recommend the use of devices fitted with vacuum pumps (type B) to reduce the risk of air pockets forming. This recommendation is particularly important for hollow tools and to guarantee perfect drying. The hot air steriliser is not recommended as it can accelerate the ageing of the spring and consequently cause modification of the torque.

**f. Storage**

After sterilisation the product must be kept in the bag that was used for sterilisation. These bags must only be opened just before use. Bags used for sterilisation are normally able to conserve the inside sterile unless the wrapping is damaged. It must be emphasised therefore that if the bag in which the products are conserved is damaged they must not be used, but re-sterilised in new bags before being used. The conservation period for sterilised products inside the bags must not exceed the period recommended by the bag manufacturer. The product must be conserved in a cool dry place, protected from direct sunlight, water and from heat sources.

**9. REFERENCE STANDARDS**

The design and production of the prosthetic components is carried out in conformity with the most up-to-date directives and harmonised norms in relation to the materials used, production procedures, information supplied and packaging.

**10. WASTE DISPOSAL PROCEDURES**

If the torque wrench is used, it must be disposed of in the same way as organic waste, according to the laws that apply locally.

**11. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY**

The directions provided by Sweden & Martina S.p.A. are supplied at the moment of treatment, and have been accepted by the Dental Practice. They must be observed and applied during all phases of use. The Warranty covers exclusively defects that are established to be attributed production-related and on submission of the piece identified by item and batch code, within validity period of the Warranty. The Warranty Conditions are available on the www.sweden-martina.com website.

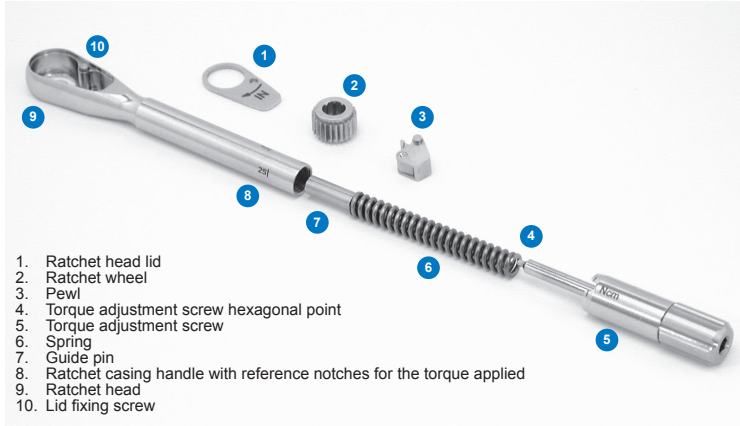
**12. DATE AND VALIDITY OF INSTRUCTIONS FOR USE**

These Instructions for Use have validity and effect from the month of July 2021.

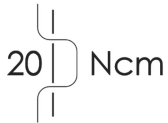
**A. Package contents**



**B. Torque wrench components**



**C. Alignment of marks for torque adjustment**



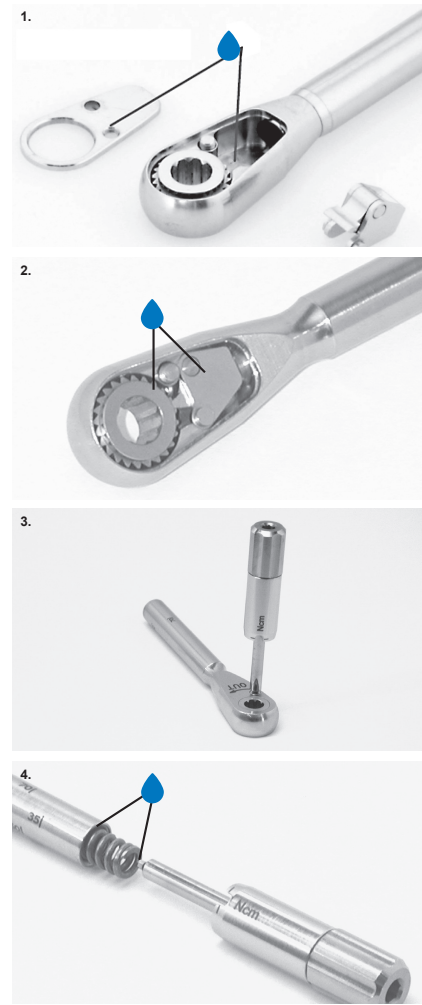
**D. Torque adjustment key**



**E. Disassembly steps of the torque wrench**



**F. Torque wrench assembly steps and parts to be lubricated**



EXPLANATION OF SYMBOLS		
	Caution! See instruction for use	✓
	Batch number	✓
	Code	✓
	Manufacturer	✓
	Country of manufacture	✓
	UDI code, Unique Device Identification	✓
	Medical Device	✓
	Consult instruction for use <a href="http://www.sweden-martina.com">www.sweden-martina.com</a>	✓
	CE marking Where applicable: The identification number of the Notified Body shall follow this symbol.	✓
	American federal law restricts this device to sale by or by order of a professional practitioner	✓
	Do not use if the packaging is damaged	✓
	Non-sterile product	✓