

Instructions for use – Torque Limiter

ORTHOMED
The Surgical Instrument Specialists

90.046

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Release
S.Witzig

Revision
C-EN

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DCN 177



Manufacturer

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DIR 93/42/EEC



Product class: I

Important notice

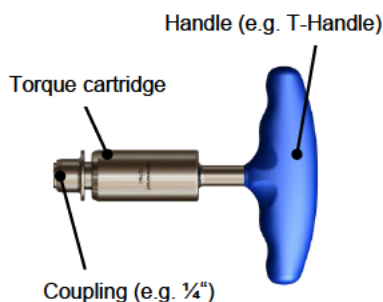


Please read these entire instructions for use thoroughly prior to using the torque limiter the first time and store them easily accessible for the user or the relevant specialist personnel. Before use, please read the information after this symbol and take article-specific information on the intended use, indication and contraindication.



Read the warnings marked with this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.

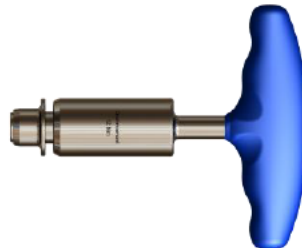
Torque limiter



Variants of torque limiter

e.g.

- Handle, Torque cartridge, Coupling



- adaptable torque cartridge, Coupling



- Handle, Torque cartridge, Ratchet, Screwdriver shaft



Scope

This operating instruction refer to the torque limiters manufactured by OrthoMed Inc. This operating instruction is copyright protected property of OrthoMed Inc. Without explicit authorization it is not allowed making unauthorized use of it or making duplicate copies.

Intended use (indication)

The torque limiters were developed for use in orthopaedic applications. They are used to limit the torque to a desired fixed value. The torque is fixed at the factory. The deviation of the actual torque from the nominal torque is $\pm 10\%$ on delivery. For nominal torques ≤ 1 Nm, the deviation is ± 0.15 Nm. Only manual operation is permitted. The specified torque is only valid for clockwise rotation.

Sample application

- For tightening bolted joints.
- For tightening bolted joints with a maximum torque.
- For tightening bolted joints with a minimum torque.
- Specific application, specified by the OP-system or the user.



Application!

- Torque limiters are adapted to the respective OP-system.
- Torque limiters must only be used with accessories from the OP-system.
- The actual medical purpose is determined by the OP-system.

Non-Intended use (contraindication)

The torque for a counter-clockwise rotation is considerably higher and not clearly defined. The employment (adaptive torque limiters) with powered or motorized drives categorized class IIa (e.g. drill) is forbidden.

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Safe handling and preparation

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, adhere to and keep the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization.
- Store any new or unused product in a dry, clean and safe place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn and fractured components.
- Do not use the product if it is damaged, defective or it has passed its recalibration/maintenance date. Set aside the product if it is damaged.



Risk of malfunction and instrument/implant failure due to improper use of the torque limiter!

- When tightening the screw connections, always work with the appropriate accessories of the operating system.
- Apply the torque limiter slowly and not jerkily until the torque is audibly triggered by a "click".
- Use rigid screw instruments to loosen the screw connection.

Couplings with push ring:

By pressing the sliding ring (A) the lock is opened and the instrument can be inserted (B). Then release the sliding ring (C) and check that the instrument is firmly seated (see Fig. 2).

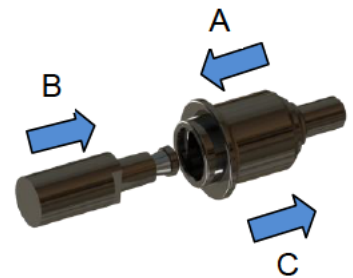


Figure 2: Sequence HU coupling

Operation



Risk of malfunction and instrument/implant failure!

- Use torque limiter only in the range of the specified nominal value.
- Carry out a functional test before each use.



Risk of malfunction and instrument/implant failure due to use of an unchecked torque limiter!

- Check recalibration/maintenance date before each use.
- Do not use torque limiter with expired recalibration/maintenance date.
- Send torque limiter with expired recalibration/maintenance date to OP system encoder or OrthoMed Inc.

Version with coupling

Couplings with pull ring:

Pulling the sliding ring (A) opens the lock and the instrument can be inserted (B). Then release the sliding ring (C) and check that the instrument is firmly seated (see Fig. 1).

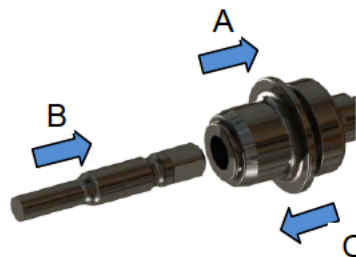


Figure 1: Sequence 1-4 coupling

Couplings with push button:

By pressing the push button (A) the lock is opened and the instrument can be inserted (B). Then release the push button (C) and check that the instrument is firmly seated (see Fig. 3).

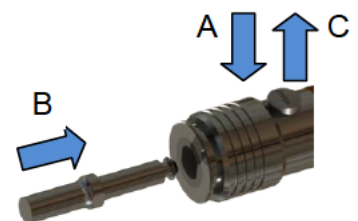


Figure 3: Sequence WA coupling with push button

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Life cycle

3 years or 6000 clicks or 250 sterilizations, from date of manufacture. The date of manufacture is indicated on the torque limiter as part of the serial number and is to be interpreted as follows:

e. g.: 05-10-032-01

05 Month of manufacture here May
10 Year of manufacture here 2010
032 Serial number (not relevant for determining the time of manufacture)
01 A sequential number that assigns a unique serial number to each torque limiter in a batch.

A torque limiter with the above serial number was manufactured in May 2010 and must be inspected, recalibrated and maintained by OrthoMed Inc. not later than May 2013. The torque is measured and any wear parts are replaced.

Recalibration/Maintenance

In order to ensure reliable operation, maintenance must be carried out according to the lifespan.

The lifespan of the torque limiters can be extended for additional 3 years through recalibration/ maintenance.

After recalibration/maintenance, the new serial number must be interpreted as follows:

e. g.: 05-10-032-01-Rev.1

05 Month of manufacture here May
10 Year of manufacture here 2010
032 Serial number (not relevant for determining the time of manufacture)
01 A sequential number that assigns a unique serial number to each torque limiter in a batch.
Rev.1 This supplement specifies the lifespan by a further 3 years. For example: manufacturing in 2010, the lifespan will expire in 2016, May.

Validated reprocessing procedure

Cleaning/disinfection

Product-specific safety instructions for the reprocessing procedure



Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- Use detergents and disinfectants according to the manufacturer's instructions,
 - Approved for plastics and stainless steel,
 - Which do not attack softeners (e.g. in silicone).
- Observe information on concentration, temperature and exposure time.
- Do not exceed the maximum permissible cleaning temperature of 96°C.

- For wet disposal, use suitable cleaning/disinfecting agents. To avoid foaming and deterioration of the effectiveness of the process chemicals: Before machine cleaning and disinfection, rinse product thoroughly with running water.
- Carry out ultrasonic cleaning:
 - as effective mechanical support for manual cleaning/disinfection.
 - for the pre-cleaning of products with encrusted residues before machine cleaning/disinfection.
 - as integrated mechanical support for machine cleaning/disinfection.
 - for the post-cleaning of products with residues that have not been removed after machine cleaning/disinfection.

Validated cleaning and disinfection process

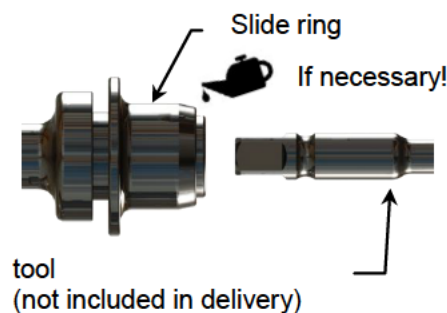


The reprocessing may only be carried out according to the reprocessing instructions "90.054".

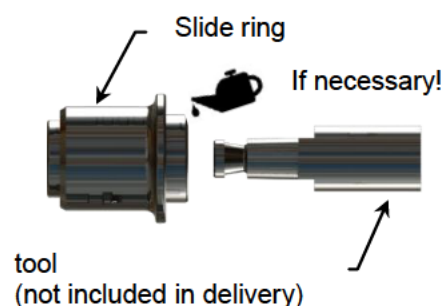
Inspection, maintenance and testing

- Allow product to cool down to room temperature.
- Check product after cleaning, disinfection and drying: Dryness, cleanliness, function and damage, e.g. corroded, loose, bent, broken, cracked, worn and broken parts.
- Dry wet or damp product.
- Check product regarding correct functionality.
- Immediately put aside damaged or non-functional products and send them to OrthoMed Inc.
- Joints, moving surfaces etc. must be lubricated with medical white oil after the reprocessing process.
- Actuate the torque limiter and check whether it triggers with an audible "click".
- Torque limiters must be recalibrated and serviced every 3 years at the latest (see service life).
- Check the slide, pull ring or push button of the couplings for good sliding properties and test the locking with the instrument.
- Check for compatibility with associated products.

Torque limiter with coupling



Example illustration: 1-4 coupling



Example illustration: HU coupling

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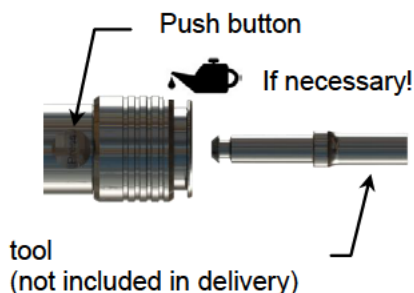
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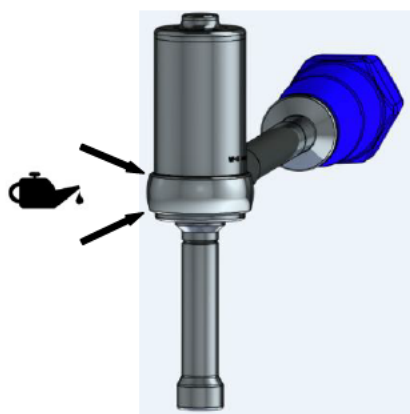
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Example illustration: WA coupling with push button

Torque Limiter with ring ratchet

For torque limiters with ring ratchet, make sure that there is smooth moving between the torque limiter and the ring ratchet.



Example illustration: Ring ratchet with screwdriver shaft

Packaging

- Pack the product in its holder or a suitable tray.
- Pack tray appropriately for the sterilization process (e.g. in sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam sterilization

- Ensure that the sterilizing agent has access to all external and internal surfaces (e.g. by unscrewing or uncoupling screw inserts, drills or other accessories).
- Validated sterilization procedure
 - Steam sterilization in fractionated vacuum or gravitational process
 - Steam sterilizer according to DIN EN 285 and validated according to 17665
 - Sterilization in fractionated vacuum at 134 °C, holding time 5 min.
- If several products are sterilized simultaneously in one steam sterilizer: Ensure that the maximum permissible load of the steam sterilizer is not exceeded according to the manufacturer's instructions.

Storage

- Sterile products should be stored in dust-proof packaging in a dry, dark and evenly tempered room.

Environmental conditions

Permitted operating temperature:
10°C to 40°C

Service



Risk of injury and/or malfunction!

- Do not modify product.

For service, maintenance and repair, please contact OrthoMed Inc. using the contact details provided. Modifications to medical equipment may result in loss of warranty and approval.

Disposal

When disposing of or recycling the product, its components and packaging, comply with national regulations.

Information and symbols on labels

REF	Article or order number
SN	Serial number (LOT + SN)
	Indication for NON sterile product
	Symbol for manufacturer
	Instruction for use
CE	CE- marking