

## SURGICAL ACCESSORIES

### Product

**Surgical accessories (Laboratory analogue, Positioning ring, Castable Box for coping, Allen key, Retentive coping for laboratory, Manual key, Ratchet, Abutment puller, Coping puller, PS Holder, PTS Holder, Insert, Handle with coping inserter, Laboratory tap, Depth Gauge, Tissue punch, Paralleling device, Pin-analogue, Transfer pin, Castable abutment, Test abutment, Extension for hex key, Surgical tray, Laboratory screw, Screw for waxing, Screw for manual key, etc.).**

For full details of available components refer to the catalogue or website [www.tfisystem.it](http://www.tfisystem.it).

**Material:** titanium, medical steel, radel, PMMA, POM, PEEK.

- The surgical accessories are supplied nonsterile and are reusable.
- The torque-adjustment ratchet is not a measuring device but a precision instrument with a range of  $\pm 10\%$  and a safety interval of 95% and can be dismantled.
- All the devices of the Easy Grip® CONE implant range are identified in the package with a product code and can be traced through a production lot number.
- The Easy Grip® implant range is continuously enhanced. T.F.I. System reserves the right to alter the design and production. Check for product updates on [www.tfisystem.it](http://www.tfisystem.it).

### Intended Use

- Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case. Some specific devices are also intended to be used by adequately trained dental technicians.
- The device is intended to be used for the preparation of the maxillary or mandibular implant site and insertion of Easy Grip® dental implants.

### Contraindications

It is contraindicated to use surgical accessories that do not belong to the Easy Grip® CONE range to position Easy Grip® implants.

### Handling precautions

- Before tightening the prosthetic components with screw, ensure the hex (or square) of the key or insert is inserted properly in the hex head of the screw, in order to prevent hex deformation. In the event of wear of the hexagonal (or square) section, it is recommended to replace the device.

- The Delrin gasket of the **CHE** hex loses functionality after 20-25 sterilisation cycles, it must therefore be replaced. This gasket must be inserted on the key until it snaps.

- To use the manual Sferoflex **ICMU** abutment key, press the piston ensuring the tongs are properly open, then insert the connection of the Sferoflex abutment in the tongs, release the piston ensuring the tongs close and completely enclose the hexagon; in this way the manual key is ready for the torsion action.

- Do not place the radel **surgical tray** to the walls of the autoclave during sterilisation cycles, as prolonged contact may cause permanent deformation.

- Before using the surgical accessory, the operator should always ascertain its mechanical integrity. If the device is not efficient, it must be immediately discarded and not reused as it is unsuitable.

- In order to assure correct operation, the torque wrench must be removed, disinfected, cleaned, lubricated and sterilised after each use.

- Due to the small size of the surgical accessories particular attention should be paid to make sure they are not swallowed by the patient. For this purpose, various accessories have a grommet hole for them to be secured to an adequate safety thread during surgery.

- The **analogues of the Easy Grip® HEX Line implants** are distinguished by two purposes:

- a) those intended for the friction-fit pre-formed abutments are made of ochre-yellow titanium
- b) those intended for castable or non-frictioning pre-formed prostheses are made of natural titanium.

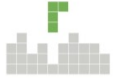
- The **PDT moulder (Easy Grip® HEX line)** can be used as a transfer for indirect impressions with the help of the VU connection screw supplied; the **VLC3** long screw must be used when using it for direct impressions.

- The **VCDM screw** should always be used in conjunction with the CDM manual key (Easy Grip® HEX line).

- The fixture/abutment coupling (friction-fit for the Easy Grip® HEX line and conometric for the Easy Grip® CONE line) is very tenacious, so when it is necessary to detach this coupling, the use of the **EM2** abutment extractor spanner (**7EM2** for the Easy Grip® CONE line) or in the case of limited operating space, the **EM** extractor screw (**7EM** for the Easy Grip® CONE line) is recommended.

- If the surgical accessory is used, it must be disposed of as biological waste to all intents and purposes and handled in accordance with local regulations.





## Instructions for use

- The operating procedures of the device are found in the Technical Operating Manual of T.F.I. System srl - also available on [www.tfisystem.it](http://www.tfisystem.it) - and in the specific instructions provided in electronic format.
- The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.
- The manufacturer cannot be held liable for the use of the medical device and the procedure followed. The responsibility for the correct and proper use of the instruments and products is therefore borne by the user. The test abutments allow the most appropriate abutment to be selected in the prosthetic planning stage.
- The optimal tightening torque for screwed Easy Grip® prosthetic components (codes PS, PP, 7PS and 7PP) and connection screws (codes VU, 7VU, VS and VUF) has been identified after appropriate study as 35 Ncm.
- The optimum torque force with which to tighten the occlusal screw is 15 Ncm for VOP, 7VOP, 7VA, 7VAL and 7VGS screws.
- The optimum torque force with which to tighten the angled channel screw 7VS is 20 Ncm.
- The optimum torque force with which to tighten the healing screw for MUA is 15 Ncm.
- The optimal torque with which to tighten the cap screws and the healing screws is 20 Ncm.
- Do not use the torque ratchet with torque values greater than 70 Ncm for the **CUD80**. Upon delivery the indicated torque values have a precision range of  $\pm 10\%$ .

## Maintenance and storage

- Prior to being used on the patient the surgical accessory must always be subjected to validated processes of cleansing, disinfection and/or sterilisation, taking care to disconnect the two components of the mucotome. The torque ratchet must undergo cleaning processes fully disassembled without using hot water.
- Immediately after use (within two hours at most) and always before cleaning the instruments, manually remove the impurities using only nylon brushes intended for the purpose, rinsing the products under cold running water ( $<40^{\circ}\text{C}$ ).
- **To clean:** place the used surgical accessories in a cleaning solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. Clean the instruments in an

ultrasonic bath, where applicable. It is recommended to use enzymatic/neutral products (see "products that are incompatible with the instruments"). Dry the instruments immediately. Never exceed the maximum temperature of  $40^{\circ}\text{C}$ . C.superare la temperatura massima di  $40^{\circ}\text{C}$ .

- **To disinfect:** place the used surgical accessories in a special disinfectant solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. It is recommended to use products containing anti-corrosive additives (see "products that are incompatible with the instruments"). Dry the instruments immediately.
- **For sterilisation:** sterilise in steam autoclave for approx. 20 minutes at standard temperature of  $121^{\circ}\text{C}$ . Once sterilisation is completed, store the sterile surgical accessories in closed containers.
- The surgical kit cannot exceed the following usage limitations: maximum time 20 minutes, maximum temperature  $135^{\circ}\text{C}$ ., pressure 2.2 bar.
- Always keep the product clean and store in a dry place, avoiding impacts that might damage it.
- Do not use the device if the packaging is damaged.

## Products that are incompatible with the instruments

When choosing the cleansing and disinfecting products, make sure they do not contain the following chemicals as they may damage the instruments:

- organic, mineral and oxidising acids (pH 5.5 is the minimum value allowed)
- strong alkaline solutions (pH 8.5 is the maximum value allowed; it is recommended to use a neutral/enzymatic cleaning agent)
- organic solvents (for example alcohols, ethers, ketones, gasoline)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- halogenated/aromatic hydrocarbons

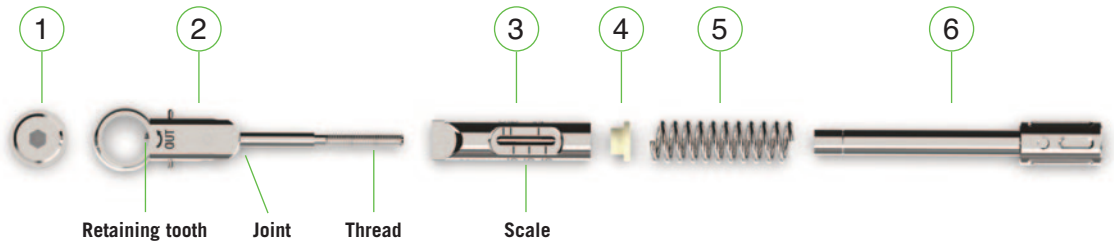
Never use harsh chemicals or ammonium-salt based chemicals.



## CUD80 TORQUE RATCHET KEY

The CUD80 torque ratchet is composed of the following elements:

1. Toothed wheel
2. Key head
3. Graduated bush
4. Washer
5. Spring
6. Adjustment nut



### Possible preliminary adjustments

- Prosthetic adjustment - torque function: by actuating the relative nut it is possible to continuously adjust the torque range by the spring. The adjustment is visible on the scale of the graduated bush.
- Surgical adjustment - blocked function: turn the adjustment nut to the  $\infty$  (infinite) reference mark. Do not tighten too much.



Warning: do not loosen both screws (X) on the adjustment nut (see figure) to avoid losing the factory setting.



### Use

By rotating the tightening torque adjustment screw (6), the torque ratchet may be adjusted according to the torque selected by the operator, ensure the reference value on the graduated bush (3) is aligned to the reading slot of the adjustment nut (6).

### Correct use of the torque applicator

- To apply the torque precisely, it is necessary to press only on the grip of the adjustment nut (see arrow in the figure).



- Apply the torque, pressing with one finger only.

- Do not grasp the grip with thumb and index finger to apply the torque.

- When the set torque is achieved, the graduated bush bends in relation to the axis on the head of the key. The application of the torque is perceived by sound and touch.

When the torque has been applied, do not press any more, otherwise the ratchet key or the dentistry components could get damaged.

When you release the grip, the ratchet key goes back to its initial position.

### Disassembly

- Before cleaning (regardless of the selected cleaning method), take apart the various components of the torque ratchet key. Disassembly does not require the use of tools, simply completely unscrew the adjustment nut (6) and take it out.

- Take care not to lose the plastic washer (4), as this would jeopardise the precision of the instrument. (The plastic washer only needs to be removed if visibly soiled. If necessary, the washer can be taken out. After cleaning, put it back in).

### Maintenance

Slightly lubricate the marked points (see the initial Figure) with suitable lubricating oil.

Be sure to only use oils that are suitable for the instruments (white paraffin oil without corrosion inhibitors or other additives), approved for steam sterilisation (taking into consideration the maximum steam sterilisation temperature (taking into consideration the maximum applied sterilisation temperature) and with confirmed biocompatibility. Always use the minimum necessary amount.

Assemble the ratchet key and run a function test. After assembly and before sterilisation, the ratchet key must be in a loosened position of max 10 Ncm.