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# UNIQA® Dental Surgical Instruments Reusable – Instructions

## 1. Device Description

- 1.1. UNIQA Dental Ltd Reusable Dental Surgical Instruments are surgical instruments made of stainless steel medical grade which are used during dental implantation and restoration procedures.
- 1.2. UNIQA Dental Ltd Reusable Dental Instruments are provided non-sterile, prior to their initial use these must be sterilized; before any subsequent use Reusable Dental Instruments must be cleaned, disinfected and sterilized with accordance to these guidelines.

## 2. Intended Use

The Cleaning, Disinfection and Sterilization guidelines covers the below listed dental instruments

### 2.1. Contra-angle driver / key for Abutments



Contra-angle driver is used for tightening screw into abutments to secure dental abutment to dental implant. This product is to be connected to a dental contra handpiece.

### 2.2. Contra-angle driver / key for Implants



Contra-angle driver is used for tightening implant placement and / or implant screw into the dental implant. This product is to be connected to a dental contra handpiece.

### 2.3. Manual\* implant driver



Manual implant driver is used primarily to place and screw the implants into the correct position. Ratchet screwdrivers are available to fit into the Ratchet and Torque Wrench.

### 2.4. Manual\* screw driver for abutments.



Manual screw driver is used for hand-tighten the healing cap and/or abutment screw to secure dental abutment to dental implant. Ratchet screwdrivers are available to fit into the Ratchet and Torque Wrench.

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**2.5. Ratchet key\* for straight MUA multi unit abutment**



Ratchet key for straight MUA is used to place and tighten the multi-unit abutment. The head of the instrument is compatible with torque ratchet wrench for better control.

**2.6. Manual\* screw driver for Implants**



Manual screw driver for Implant is used for tightening implant placement and / or implant screw into the dental implant.

**\*Note:** All manual screw drivers/keys are compatible with torque ratchet wrench for better control.

**2.7. Manual punch tool**



Manual punch tool is used for manual removal of soft tissue.

**2.8. Parallel pin**



Parallel pin is used for checking the placement of the dental implant and making it as parallel as possible.

**2.9. Handle for angled MUA multi unit abutment**



Accessory for holding MUA and place it into dental implant. Not used for screwing.

**2.10. Surgical guide sleeves**



Guide Sleeves are intended for assisting manufacturing of the surgical guide. The Surgical guide Sleeve, is a special accessory for the 3D printed template surgical guide frame. The 3D printed template surgical guide frame is designed to deliver accurate implant planning schematics

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and custom-designed guided surgery templates, for a more precise surgical procedure and predictable prosthetic results. It is intended to define the position, direction and height/depth of surgical sites.

2.11. **Extractor for Abutment**



Extractor for angled MUA abutment is used to release a "locked" abutment from an implant.

2.12. **Depth probe**

Depth probe is intended to verify the depth of an osteotomy during dental implant surgery and to measure the gingival height following external fixture grafting.

The depth gauge is a two sided probe:

1. Measures the Gingival Height – can be used to measure the gingival height following external fixture grafting. After implant placement insert the depth probe into the implant to verify the gingival height to choose the appropriate abutment, healing cap. Each marking groove above the implant level (0), as marked at figure 1, has 1mm step - 0 to 7mm.
2. Measures the Osteotomy Depth - can be used during the preparation of an osteotomy to verify the depth by measuring the drilling depth. After drilling insert the depth probe into the osteotomy until the probe is seated at the bottom of the osteotomy. The depth groove marking corresponds UNIQA’s desired implant length 6 to 16mm.

See figure 1.

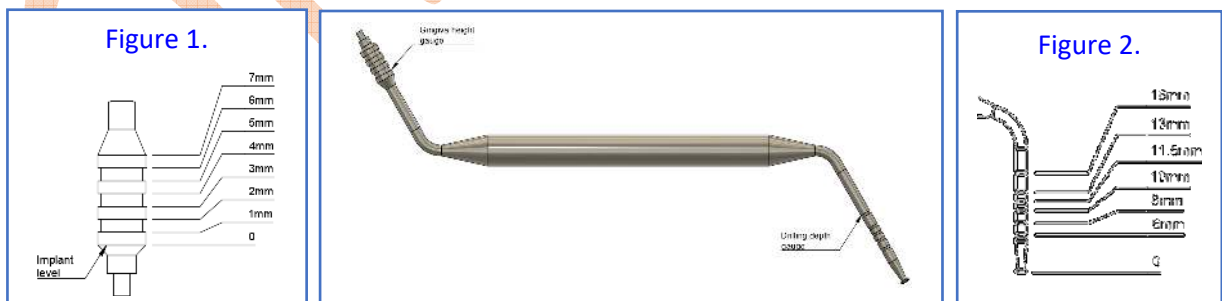


Figure 1. Depth Probe

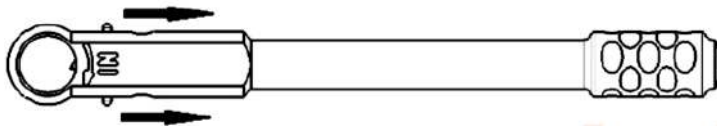
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**2.13. Ratchet wrench**


Ratchet wrench is used to tighten or loosen threaded implants into the prepared osteotomy site. This application is enabled by connecting the Manual drivers / keys head to the ratchet. The ratchet is without torque function. The ratchet consist of just two individual parts and can therefore be dismantled for preparation in a few seconds.

**Possible default settings**

Surgery setting – ratchet function available but without torque function

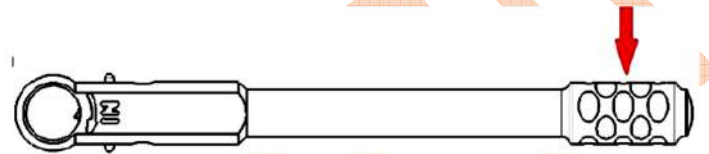


**Change tool (adaptor)**

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)

**Correct handling**

The pressure point is only on the end of the handle (see arrow in)



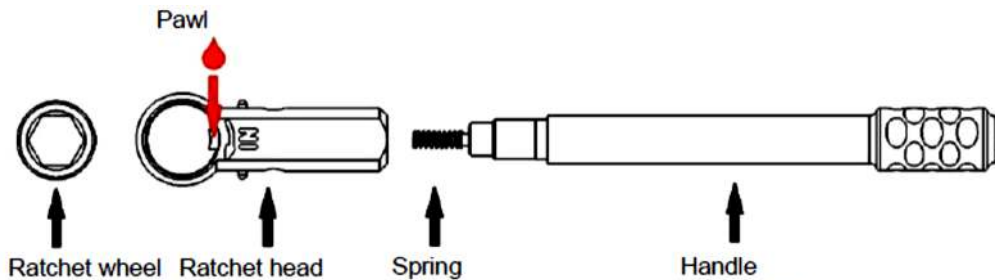
Apply pressure in direction of arrow with only one finger. (See arrow in)




**Cleaning Preparation for Re-Use**

Before initiating cleaning procedure the ratchet must be disassembled into its individual parts before being cleaned. The handle must be completely removed. The components and ratchet wheels must be removed from the ratchet head. See below figure.

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**Maintenance**

Lightly lubricate the areas marked with  using contra-angle handpiece oil. Assemble ratchet and carry out functional test.

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.

**2.14. Torque ratchet wrench**

Torque ratchet wrench is hand instrument used in implantology and prosthetic as below specified.

The torque ratchet is without bending arm and can be adjusted before the intervention on the patient.


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.

For implements with ranges up to 80 Ncm → Using with loads above 100 Ncm can damage the implement.


For implements with ranges up to 100 Ncm → Using with loads above 120 Ncm can damage the implement.

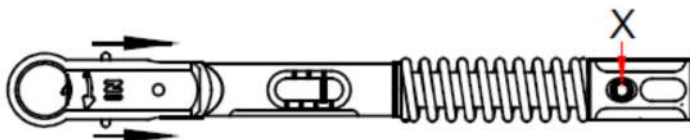
**Possible default settings**

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.

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Do not loosen either of the screws  on the adjusting nut, as this leads to a loss of the factory default settings.

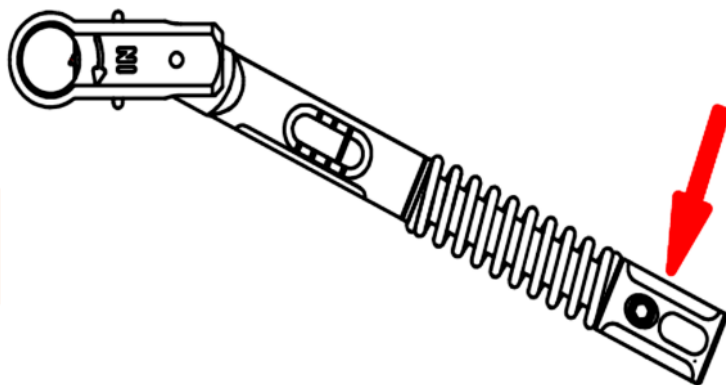


### Change tool (adaptor)

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 above Figure)

### 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.

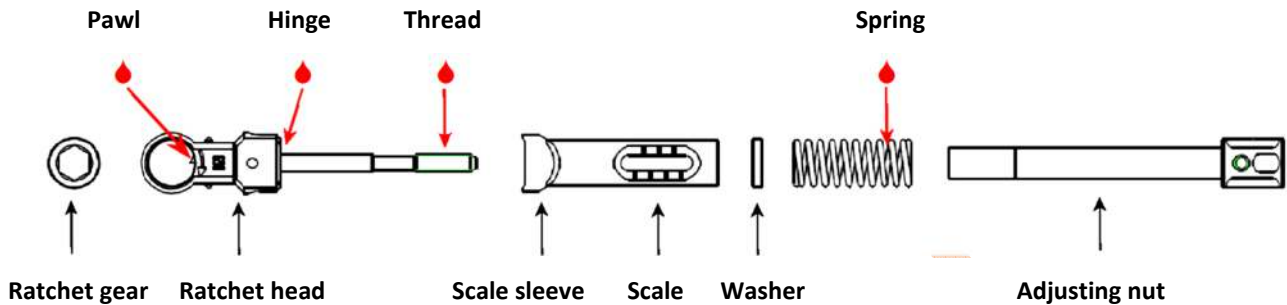


### Cleaning Preparation for Re-Use

Before initiating cleaning procedure the torque ratchet must be disassemble, only the adjusting nut must be completely removed. Do not lose the plastic disc during this process, as this will impair the precision of the implement. (The plastic discs need to be removed only if there is visible contamination. The disc can be removed in needed. Push the disc back in after cleaning).

See below figure:

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**Maintenance –**

Lightly lubricate the areas marked with using contra-angle handpiece oil. Assemble ratchet and carry out functional test.

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. 10 Ncm after being assembled and before being sterilized.

In delivered condition the torque ratchet has an accuracy of ± 10% with regards to the adjustable torque value. UNIQA Dental ltd doesn't offer repair services.

**2.15. Dental Drills**



Dental drill is used for surgery applications in the upper or lower jawbone. This product is connected to a dental contra handpiece. Drill Accessories assist the Implant Drill in its use.

**Warning**

- Inspect the drill for damage or wear before each use and discard any damaged drills.
- Ensure that the drill is fully seated and gripped in the handpiece collet before use.
- Maintain handpiece in good working order and correctly lubricated.





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- Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures.
- Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.
- Do not exceed the maximum speeds indicated below.
- Avoid excessive drilling speed and/or drilling duration in order to avoid overheating and associated complications.
- Move the drill continuously when in use to avoid localized heating.
- Over time, repeat sterilizations may affect cutting efficiency and color appearance.
- Cutting edges should present a continuous edge and appear sharp.
- Check the latch lock shank for wear to ensure the connection is not damaged. If inspection reveals signs of wear, damage, or unrecognizable color identification, replace the drill accordingly.
- Non-binding recommendation, we advise 6 – 10 uses at the maximum.

**Instructions**

- Drills are marked with sizes and color-coded for ease of identification.
- Drilling procedures should be performed at maximum 800 – 1300 RPM with copious irrigation.
- The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential.
- For Surgical Procedures refer to UNIQA’s Surgical & Prosthetic User Manual TF-MDR-1000-17.3.

**Cleaning**

- Follow below cleaning, disinfection & sterilization instruction as set out in this manual.
- During the cleaning process ensure the following:
  - Flush the drill lumen with a hypodermic needle.
  - Use a nylon brush to rid the drill of additional debris caught in the irrigation channel.

**2.16. Kit Boxes**

Kit boxes are convenient storage for dental instruments. Kit boxes are used to organize, enclose, sterilized, transport and store dental instrument during dental surgical procedures. UNIQA Kit boxes contains: Torque Ratchet, Dental Drill burs, Marking Drill, Drill Extension, Manual Screw Driver for abutment/implant, Ratchet Driver for Abutment, Ratchet Driver for Implant, Parallel Pins, Depth Gauge, Contra Angle driver/key for abutment, Contra Angle driver/key for implants, Drill Stoppers.

**Warning**

- The material may change color tone on prolonged exposure to UV light.

**Cleaning**

- Follow below cleaning, disinfection & sterilization instruction as set out in this manual.





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- Use mild detergents even if cleaning is done using ultrasound equipment.
- Dry the boxes with a soft cloth.
- Do not use abrasive sponges or metal parts that might damage the surface of the box.

**3. Intended Users and Patient Groups**

- 3.1. UNIQA Dental Surgical Instruments are intended to be used by dental health care professionals.
- 3.2. UNIQA Dental Surgical Instruments are intended to be used in partially and/or fully edentulous patients subject to dental implantation and/or restoration treatment.

**4. Handling Procedure**

- 4.1. The complete handling procedures - UNIQA’s Surgical & Prosthetic User Manual (TF-MDR-1000-17.3) are available on the website <https://uniqa.dental/>.
- 4.2. The electronic catalog of UNIQA’s products is available on the website <https://uniqa.dental/>.
- 4.3. Recommendation for tightening and insertion limits with the use of contra angle keys/drivers, manual screw drivers and use of ratchets / torque ratchets, all with accordance to their intended use:
  - The tightening of the healing abutment on the implant 5-10 Ncm.
  - The tightening of the abutment screw on the implant analog 10-15 Ncm.
  - The tightening of the abutment screw on the implant 30-35 Ncm.
  - Implant installation for desired position use insertion torque max 50 Ncm. Do not exceed 50 Ncm. For immediate function, the implant should be able to withstand a final torque between 35-45 Ncm.

**5. Materials**

- 5.1. Contra-angle driver/keys, Manual implant drivers, Manual screw drivers for abutments, Punch tool, Parallel pin, Handle for MUA, Surgical guide sleeves, Extractor for Abutment, Depth probe, Ratchet wrench, Surgical guide sleeves, Extractor for Abutment, Dental Drills, Dental Stoppers – Surgical Stainless steel. Dental Drills may be Stainless Steel with or without DLC diamond like carbon coating by pure Ti (Titanium).
- 5.2. Ratchet screws/key - Stainless steel with plastic O-ring.
- 5.3. Torque ratchet wrench - Stainless steel with PEEK.
- 5.4. Kit Box – High grade plastic PPSU RADEL and Silicon.

**6. Contraindications**

- 6.1. Specific contraindications can only be seen in connection with operation procedures, please refer to dental implant or dental abutment Instructions for Use.
- 6.2. Contraindications are applied in the following cases:



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Patients allergic or intolerance or hypersensitive to stainless steels.

Patients unfit for operation and/or surgical procedures.

- 6.3. It is the responsibility of the physician to select the suitable methods and settings in accordance with the individual anatomical and medical characteristics of their patients.

## 7. Warning

- 7.1. UNIQA Dental Ltd Dental Instruments are intended for use by trained dental specialists.
- 7.2. Use of dental instruments not clean, not disinfectant and non-sterile may lead to infection of tissues or diseases.
- 7.3. For small size devices, components and detachable devices attention must be made to not swallow or aspirated by patient. Use your supporting medical devices to prevent aspiration or salivary e.g. throat shield.
- 7.4. If the sterile packaging of the instrument is damaged in such case reprocess the device before use.
- 7.5. Non sterile Dental Surgical Instruments may lead to infection of tissues or infectious diseases.
- 7.6. UNIQA Dental Ltd Dental Instruments have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the UNIQA Dental Ltd Dental Instruments in the MR environment is unknown.
- 7.7. The sterilizer manufacturer's written IFU should be followed for operation of the sterilizer and indications for use.

## 8. Limitation on Processing

- 8.1. A specific shelf life for dental instrument cannot be given as this is being determined by various parameters including cleaning, disinfection & sterilization. End of life is normally determined by wear and damage due to use as provided in this guidelines.
- 8.2. For dental drills, Non-binding recommendation, we advise 6 – 10 uses at the maximum.

## 9. Adverse Effects

- 9.1. No adverse effects will occur, provided that the indications are complied with.

## 10. Precautions

- 10.1. Before each procedure check the conditions of the dental surgical instruments, always respecting their useful life. Replace the instruments if there is damage, markings deleted, sharpening jeopardized, deformation and wear.
- 10.2. Excessive use of force and/or disposition of the surgical instrument can lead to the fracture of the instrument or component, making the procedure unfeasible.



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- 10.3. Before Surgery careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.
- 10.4. After Surgery in order to ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after surgery and implant treatment and to inform the patient about appropriate oral hygiene.
- 10.5. UNIQA Dental ltd has evaluated two methods for cleaning and disinfection of dental surgical instruments: (1) Manual Method (2) Automated Method as detailed in these guidelines. It is the responsibility of the user/processor to ensure following these guidelines in order to process the dental surgical instruments properly.
- 10.6. It is recommended that dental surgical instruments and/or kit boxes be processed as soon as is reasonably practical following use in order to avoid drying of residues.
- 10.7. It is the responsibility of the user/processor to follow the detergent solutions manufacturer’s instructions for use for reference of the concentration, temperature and contact time. UNIQA Dental does not recommend solutions for use, but rather indicates the type that was used for validation.
- 10.8. Protective clothing and equipment instructions should be followed by the cleaning agent manufacturer for correct handling and use of the product.
- 10.9. Recommended use for Water Quality – freshly purified water, highly purified water or sterile water.
- 10.10. For US Market: Use FDA cleared sterilization pouch & accessories

**11. Point of use**

- 11.1. Use protective clothing, equipment and sterile gloves.
- 11.2. Use tweezer to handle the dental instrument, kit box in order to avoid contamination.
- 11.3. Remove gross soil, blood and tissue using absorbent paper wipes.
- 11.4. Apply intensive rinsing of the dental instruments with running water.
- 11.5. Dispose any worn out, damaged dental instruments.

**12. Transport**

- 12.1. Dispose dental instruments in a designated container with accordance to local regulations.
- 12.2. It is recommended that dental instruments, kit boxes will be reprocessed as soon as possible.
- 12.3. In case of delayed reprocessing, store the dental instruments in a closed box, or place then in tray covered with damp cloth in order to avoid drying of soil and / or debris.
- 12.4. Longer delays require immerse of the dental instruments in a bath of a lukewarm cleaning solution.



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### 13. Preparations before Cleaning

13.1. Disassemble dental instruments as applicable:

- Torque ratchet wrench - see in section 2.
- Dental drills – in case of using drill stoppers these must be disassembled.
- Ratchet key for MUA
- Kit boxes

13.2. Cleaning processing should be performed as soon as practical. In case of delay recommended is to cover the dental instruments with a damp cloth or store them in closed boxes in order to avoid drying of soil and / or debris. Longer delays require immerse of the dental instruments in a bath of a lukewarm cleaning solution (Enzymatic Detergent solution) to avoid the drying of soil and/or debris.

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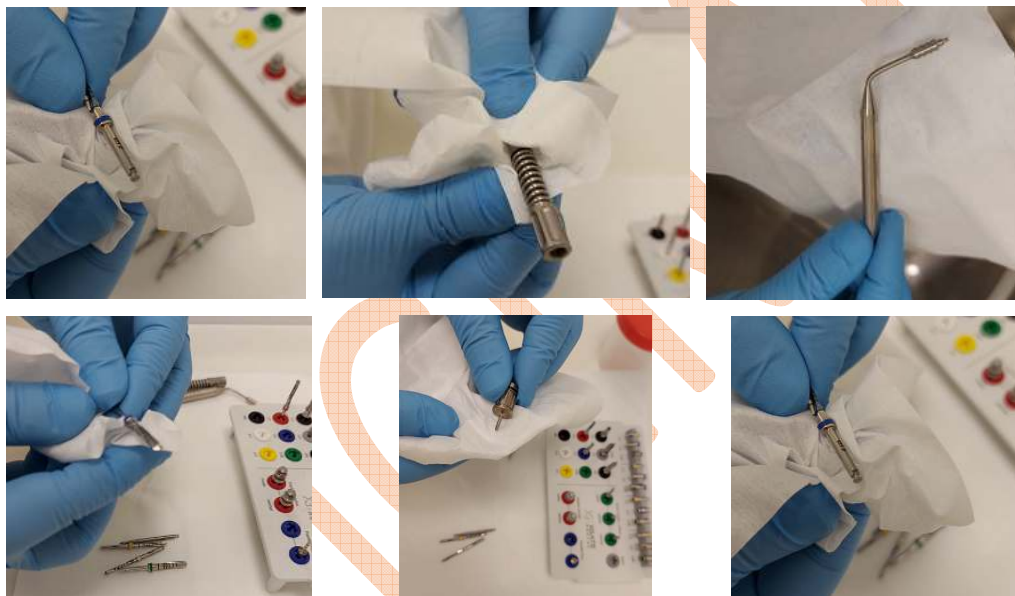
**14. Manual and Mechanical cleaning using ultrasonic cleaner**

14.1. **Pre-Cleaning for Manual Cleaning Process**

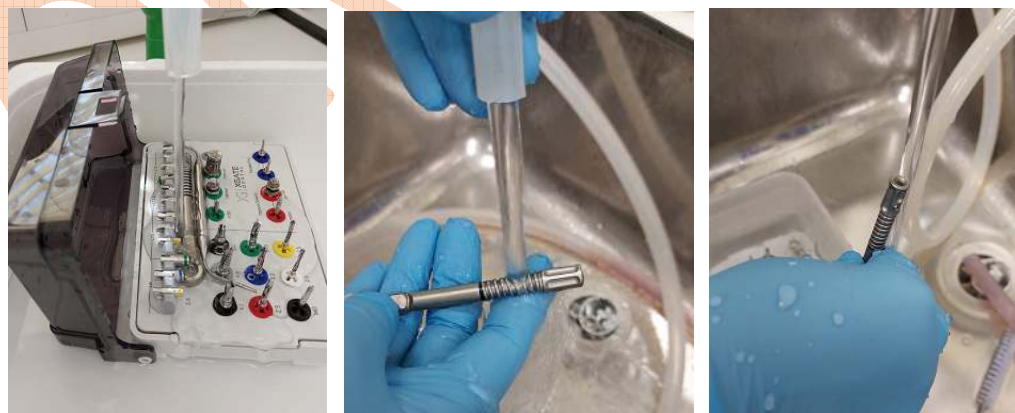
14.2. Equipment and Accessories:

- Ultrasonic bath frequency 40-50kHz
- Cleaning agent follow detergent manufacturer’s instructions.
- Syringe 10ml, Hypodermic needle, Soft Bristle brush (diameter 0.5 cm X Length 6.0 cm or diameter 1.0 cm X Length 9.0 cm or L1.5cmXW3.5cm), absorbent paper wipes.

14.3. Gross soil, blood and tissue have to be removed using absorbent paper wipes



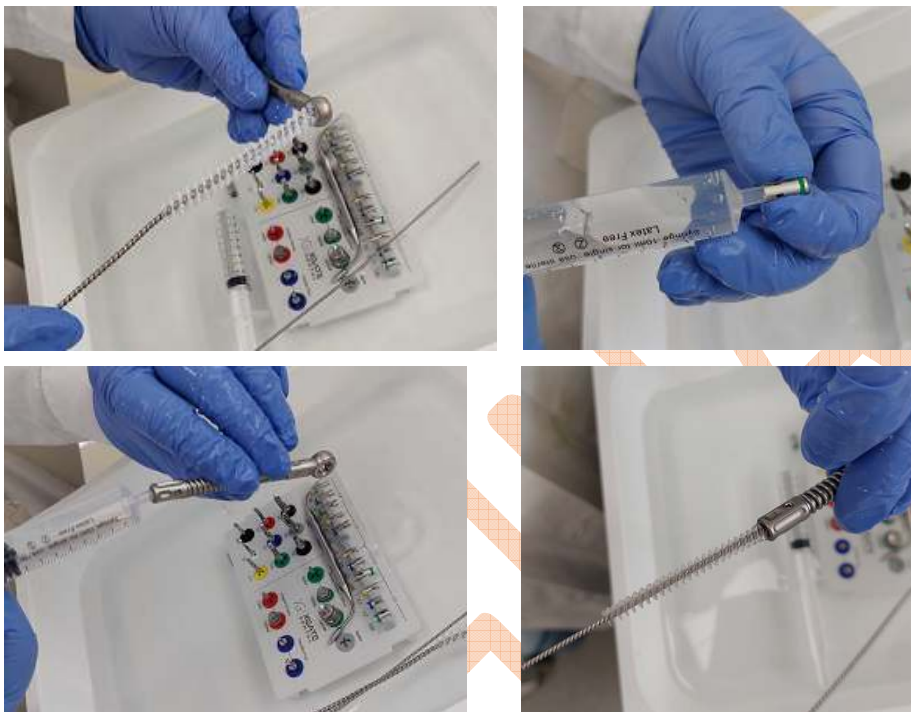
14.4. The dental instruments have to be intensive rinsed with running water.





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14.5. Any soil 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).



14.6. Dental Instruments, which require disassembling, must be disassembled prior to cleaning e.g. Ratchet key for MUA, Ratchet Wrench, Torque Ratchet Wrench, dental drills from stoppers, convenient kit boxes. In case of kit boxes, these must be completely disassembled before cleaning and disinfection.

14.7. Improper dental instruments should be disposed in container following local health regulations.

14.8. For Visual Inspection during process follow below aspects:

- Clean surface without any debris;
- Device surface – no discoloring, corrosion or rust;
- Device completeness – no broken parts, cracks, cutting edges dull, worn out, disassembling parts, fitting deformed;
- Special care during inspection for the following: mating surfaces, channels, threads, drill flutes.
- Where needed conduct functional inspection for the instrument.

Note: For Visual Inspection it is recommended to use a lighted magnifying glass.

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14.9. For Cleaning process provided hereby below two methods: Manual Cleaning and Disinfection Method and Cleaning and Disinfection using Automated Thermodisinfectors method, where practical use the Automated Thermodisinfectors method.

14.10. **Manual Cleaning Procedure**

14.11. Use an ultrasonic bath frequency 40 kHz, instructions for use with accordance to the manufacturer recommendation.

14.12. Cleaning agent (Enzymatic Detergent solution - Powerzyme 1ml/L was used by UNIQA) intended for manual cleaning and for ultrasonic treatment – concentration with accordance to the manufacturer IFUs.

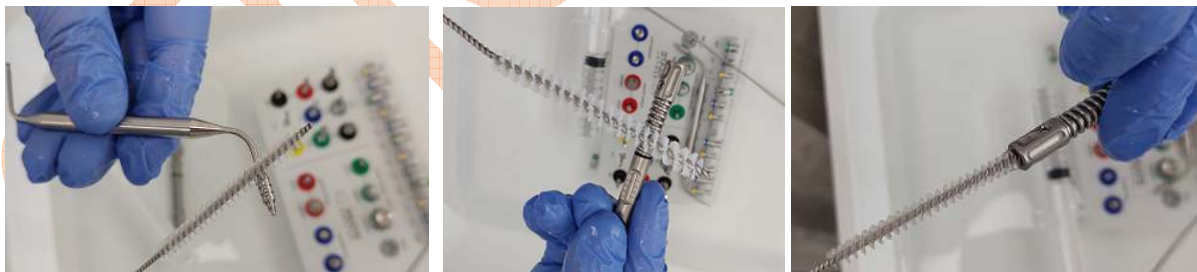
14.13. Accessories used during cleaning: Irrigation needles, Soft nylon brushes, syringes, absorbent cloths etc.

14.14. Prepare purified water, highly purified water or sterile water for the rinsing application.

14.15. Remove debris (tissue/bone) by immersion the dental instruments in lukewarm water <40°C/104°F. Keep the dental instruments in a wet environment until the next step.

14.16. Immerse the dental instruments in an enzymatic cleaning solution (Enzymatic Detergent solution - Powerzyme 1ml/L solution was used by UNIQA) prepared with lukewarm tap water cleaning solution was used with accordance to the manufacturer recommendation.

14.17. Scrub the dental instruments using soft bristled nylon brush under cold tap water till all visible debris and soil are removed. Ensure scrubbing from all sides (internal/external), with attention to prevent any damage to the dental instruments.



14.18. Flush the internal channels with cleaning solution using irrigation needle connected to a syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.

14.19. Immerse the dental instruments in ultrasonic bath with a cleaning solution (Enzymatic Detergent solution, Powerzyme, 1ml/L, 10 minutes at 40°C/104°F was used by UNIQA). Use cleaning solution with accordance to the manufacturer recommendation.



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- 14.20. Rinse the dental instruments, kit box with water (purified, highly purified or sterile) for at least 1 minute for removal of cleaning solution traces.



- 14.21. Flush the internal channels with water (purified, highly purified or sterile) using irrigation needle connected to a syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.



- 14.22. Carry out visual inspection, where applicable, in case of remain soil / debris on dental instrument surface repeat cleaning process as above described.

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**15. Mechanical and Automated cleaning using ultrasonic cleaner and washer machine**

15.1. **Pre cleaning for Automated Thermodisinfector procedure**

- 15.2. Use ultrasonic bath frequency 40 kHz.
- 15.3. Prepare cleaning solution (Used by UNIQA solution of neodisher® MediClean)with accordance to manufacturer instructions.
- 15.4. Accessories used during cleaning: Syringe 10ml, Hypodermic needle, Soft Bristle brush (diameter 0.5 cm X Length 6.0 cm or diameter 1.0 cm X Length 9.0 cm or L1.5cmXW3.5cm), absorbent paper wipes.
- 15.5. Prepare purified water, highly purified water or sterile water for the rinsing application.
- 15.6. Remove debris (tissue/bone) by immersion the dental instruments in lukewarm water <40°C/104°F. Keep the dental instruments in a wet environment until the next step.



- 15.7. Immerse the dental instruments in an enzymatic cleaning solution (neodisher® MediClean (2ml/L) for 10 minutes at max 40°C/104°F was used by UNIQA) prepared with lukewarm tap water leaning solution was used with accordance to the manufacturer recommendation.
- 15.8. Scrub the dental instruments using soft bristled nylon brush under cold tap water till all visible debris and soil are removed. Ensure scrubbing from all sides (internal/external), with attention to prevent any damage to the dental instruments.



- 15.9. Flush the internal channels with cleaning solution using irrigation needle connected to a 10ml syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.

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- 15.10. Rinse dental instruments, kit box with cold tap water (purified, highly purified or sterile) for at least 1 minute for removal of cleaning solution traces. Water rinse should be made three times, for each cycle use fresh clean water.



- 15.11. Flush the internal channels with freshly water (purified, highly purified or sterile) for at least 1 minute using irrigation needle connected to a syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.



- 15.12. Dry the dental instrument using medical compressed air and lint free single use wipes. Avoid leaving any water in hollow spaces blow out with sterile, oil-free pressurized air.
- 15.13. Carry out visual inspection and where needed repeat the manual cleaning and disinfection procedures.

### Inspection

- 15.14. The cleaned dental instruments will be visually inspected for:
- Clean surface without any debris of soil;
  - Device surface – no discoloring, corrosion or rust;
  - Device completeness – no broken parts, cracks, cutting edges dull, worn out, dissembling parts, fitting deformed;
  - Special care during inspection for the following: mating surfaces, channels, threads, drill flutes.
  - Where needed conduct functional inspection for the instrument.
- 15.15. After inspection assemble the dental instruments which need to be assembled and then pack each dental instrument in a separate sterilization pouch.

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15.16. **Automated Cleaning**

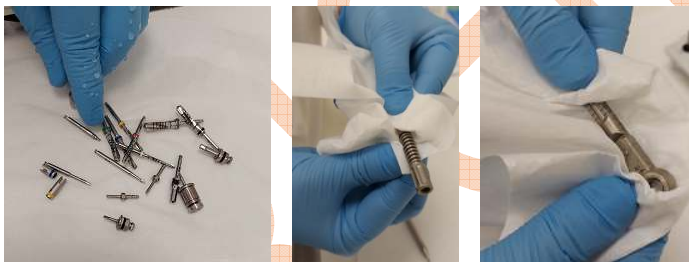
15.17. Place the dental instruments in a tray and load them into the disinfecter, use the disinfecter with accordance to the manufacturer recommendation.

15.18. Activation of Cleaning running cycles with accordance to the following validated parameters:

Miele PROFESSIONAL, PG 8593; cleaning program “ALKLINE”

- 2 Minutes pre-cleaning with cold tap water
- 5 Minutes cleaning at 55°/131°F tap water with solution of alkaline cleaning agent (Neodisher® MediClean used by UNIQA) and Drain.
- 3 Minutes neutralization with tap water and Drain.
- 2 Minutes intermediate rinsing with cold tap water and Drain.
- Thermal disinfection at 90 °C (± 5°C) with a 5 min and Drain.
- Dry external side of the dental instrument using the drying cycle of the disinfecter (30 Minutes at 100°C).

15.19. Dry the dental instrument using medical compressed air and lint free single use wipes. Avoid leaving any water in hollow spaces blow out with sterile, oil-free pressurized air.



15.20. Carry out visual inspection and where needed conduct functional inspection for the instrument.

15.21. After inspection assemble the dental instruments which need to be assembled and then pack each dental instrument in a separate pouch.

**Inspection**

15.22. The cleaned dental instruments. Kit box, will be visually inspected for:

- Clean surface without any debris of soil;
- Device surface – no discoloring, corrosion or rust;
- Device completeness – no broken parts, cracks, cutting edges dull, worn out, dissembling parts, fitting deformed;
- Special care during inspection for the following: mating surfaces, channels, threads, drill flutes.
- Where needed conduct functional inspection for the instrument.



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- No residue of soil or defects on the cleaned test article based on visual inspection
- 15.23. After inspection assemble the dental instruments which need to be assembled and then pack each dental instrument in a separate sterilization pouch.

**16. Manual Disinfection Procedure**

- 16.1. Use ultrasonic bath with disinfection solution (0.3% Cidex Opa at 20°C (68°F) with an immersion time of at least 15 minutes for a reuse period of up to 14 days – was used by UNIQA). Use disinfection solution with accordance to the manufacturer recommendation.
- 16.2. Immerse the dental instruments and ensure that the entire surface external/internal is covered with the solution for the time length with accordance to the disinfection solution manufacturer recommendations.
- 16.3. Flush the internal channels with disinfection solution using irrigation needle connected to a 10ml syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.
- 16.4. Rinse dental instruments, kit box with water (purified, highly purified or sterile) for at least 1 minute for removal of disinfection solution traces. Water rinse should be made three times, for each cycle use fresh clean water.
- 16.5. Flush the internal channels with freshly water (purified, highly purified or sterile) for at least 1 minute using irrigation needle connected to a syringe. For dental drills with irrigation ensure the irrigation needle to pass the silicone barrier in the middle of the drills.
- 16.6. Dry the dental instrument using medical compressed air and lint free single use wipes. Avoid leaving any water in hollow spaces blow out with sterile, oil-free pressurized air.
- 16.7. Carry out visual inspection and where needed repeat the manual cleaning and disinfection procedures.

**Inspection**

- 16.8. The cleaned dental instruments will be visually inspected for:
  - Clean surface without any debris of soil;
  - Device surface – no discoloring, corrosion or rust;
  - Device completeness – no broken parts, cracks, cutting edges dull, worn out, dissembling parts, fitting deformed;
  - Special care during inspection for the following: mating surfaces, channels, threads, drill flutes.
  - Where needed conduct functional inspection for the instrument.





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**17. Packaging**

17.1. Seal instruments, kit box within sealed protective packaging complies with ISO 11607-1 requirements.

**18. Sterilization**

18.1. Use following Steam Sterilization instructions with accordance to ISO 17665:

- Use an autoclave with accordance to the manufacturer’s instructions
- Pre-vacuum air removal
- Seal single device in a pouch; *For US Market: use FDA Cleared pouch;*
- Temperature 132°C (270°F) , Temperature Max 137°C (279°F)
- Exposure time 4 minutes
- Drying time 20 minutes in chamber.

**Inspection**

18.2. The cleaned dental instruments will be visually inspected for no defects (signs of corrosion, color change, distortions, fractures, etc) on the sterile dental instruments.

**19. Clinical Benefits and Undesirable Side Effects**

Clinical Benefits associated with UNIQA Dental Surgical Instruments:

UNIQA Dental Surgical Instruments consists of: Contra-angle driver / key for Abutments, Contra-angle driver / key for Implants, Range of Dental Drill Burs, Manual implant driver/Ratchet screw driver, Manual screwdriver for abutments/Ratchet screw driver, Ratchet key for straight MUA multi unit abutment, Manual punch tool, Parallel pins, Handle for Angled MUA Multi Unit Abutment, Surgical guide sleeves, Extractor for Abutment, Depth probe, Ratchet wrench, Torque Ratchet Wrench.

UNIQA Dental Surgical Instruments are used as accessories during surgical implantation procedures and restorative applications. The clinical benefits arising from these procedures are to restore missing teeth, restore missing crown and restoring patient chewing function.

Undesirable Side Effects associated with UNIQA Dental Surgical Instruments:

UNIQA Dental Surgical Instruments are used during an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. Depending on location it may also lead in rare cases to fenestration or fracture of bone, perforation of neighboring structures, sinusitis, or sensory/motor disturbances.

During use of these devices, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.



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In respect use with UNIQA Dental Drills, the surgical implantation procedure involves risks which may be associated with typical side effects such as localized swelling, infection, inflammation, tenderness of short duration, edema and hematoma or bleeding. Numbness of the lower lip and chin region following lower jaw surgery and of the tissue beside the nose following upper jaw surgery is a possible side-effect of the surgery.

### Serious Incident Notice

For a User/Patient/third party in the European Union and in countries having identical regulatory requirements, in the case of during use with this device or as results of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

## 20. Storage

- 20.1. Store dental instruments individually or in sets in clean, dry place and protected against dust, chemical fumes or components in order to prevent recontamination.
- 20.2. Avoid all effects that could affect the product marking, shelf life, surface or geometry shape such as unnecessary commotion, strains, heat, UV radiation, moisture, etc.
- 20.3. It is recommended to place dental instruments in covered trays, cassettes or clip-in trays in enclosed boxes or cupboards in a rack system, or sealing within clean, single-use, sterilization grade wrapping material or self-seal sterilization bags/pouches.

## 21. Disposal

- 21.1. Disposal of unused, damaged dental instruments with accordance to local regulations and environmental requirements.

The instructions provided above have been validated by UNIQA DENTAL LTD as being capable of preparing a medical device for reuse. According ISO 17664-1, ISO 17665 It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Any deviation from these instructions made by the processor must be properly evaluated for effectiveness and potential adverse consequences.

Disclaimer: UNIQA Dental is not liable for any damage or injury caused by misuse, improper reprocessing or handling.

### References:

Steam steriliser should comply with the maintenance and validation requirements as set out in EN 13060, EN 285, ISO 17665-1, AAMI ST79 or local standards;

21 CFR 58 Good Laboratory Practice for Non-clinical Studies;





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AAMI TIR 12 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers;

AAMI ST98 Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices;

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities;

ISO 17664-1 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices;

ISO 17665-1 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;

**Basic UDI-ID Information:**

<b>Product</b>	<b>Basic UDI-ID Number</b>
Dental Drill Burs	729011285DrillQ7
Drills with external irrigation	729011285DrillQ7
Drills with internal irrigation	729011285DrillQ7
Conical Drills with external irrigation	729011285DrillQ7
Countersink drill	729011285DrillQ7
Drill Extender	729011285DrillQ7
Drill Stopper	729011285DrillQ7
Lance Drills	729011285DrillQ7
Marking Drills	729011285DrillQ7
Round Burr	729011285DrillQ7
Step Drills coated	729011285DrillQ7
Twist Drills coated	729011285DrillQ7
Tissue punch drill	729011285DrillQ7
Trephine burr	729011285DrillQ7
Drill with integral stoppers	729011285DrillQ7
Contra angle key for straight MUA	729011285DInstrumentICA3U
Contra-angle driver for abutments	729011285DInstrumentICA3U
Contra-angle driver for implants and cover screw	729011285DInstrumentICA3U
Manual implant driver/Ratchet screw driver	729011285DInstrumentRTT
Manual screwdriver for abutments/Ratchet screw driver	729011285DInstrumentRTT
Ratchet key for straight MUA multi unit abutment	729011285DInstrumentRTT
Manual punch tool	729011285DInstrumentRTT
Parallel pins	729011285DInstrumentRTT
Handle for Angled MUA Multi Unit Abutment	729011285DInstrumentRTT
Surgical guide sleeves	729011285DInstrumentRTT
Extractor for Abutment	729011285DInstrumentRTT
Depth probe	729011285DInstrumentRTT
Ratchet wrench, Torque Ratchet Wrench	729011285DInstrumentJGU8



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**Determination of end of instrument shelf life:**

A direct value for reusable instruments cannot be given. The shelf life of an instrument depends on a number of factors during use as well as cleaning and sterilization. Dental Instruments are not design for rework therefore the following guidelines should be used for determination of end of instrument shelf life:

Corrosion and or Rust	Dental Instruments with corrosion and/or rust must be discarded. Look thoroughly in external and inner sided of the dental instrument.
Broken	Dental Instruments that have broken edges, broken tips, broken assembling parts, broken connection, broken instruments - must be discarded.
Torn O-Rings	Torn O-Rings are not replaceable thus the dental instrument must be discarded.
Disassembling	Disassembled parts, detached parts which cannot be assembled back – then the entire dental instruments must be discarded.
Deformation	Deformed dental instrument, dental instruments which have deformed part, deformed edge - must be discarded.
Incomplete	Dental Instrument missing part, has a damage, broken/twisted part / side / surface, having missing part, worn out parts - must be discarded.
Sharp	Dental Instrument designated to have sharp edge, parts – where Sharpe edge become slight round or losing their sharp edge - - must be discarded.
Worn out, dull	Dental Instruments which their hex, edge, movement, functionality is worn out - must be discarded.

 Manufacturer: UNIQA DENTAL LTD  
2 Ha-Tsoran street, Netanya 4250602, Israel  
Phone: 972-77-7827367 [www.Uniga.Dental](http://www.Uniga.Dental)



Prescription device: Rx Only  
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

 Authorized European Representative: OBELIS S.A.  
Bd. Général Wahis, 53 , 1030 Brussels, Belgium  
Tel: +32.2.732.59.54 Email: [mail@obelis.net](mailto:mail@obelis.net)



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Symbols Glossary:

The following symbols may be presented on the device labeling or/and accompanied information.

	Catalogue Number		Lot Number
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Manufacturer Details		Authorized Representative in the European Community
	CE Mark		Medical device
<b>Rx only</b>	Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.		Unique Device Identifier
	Date of manufacture		Keep dry
	Sterilized using irradiation		Non sterile
	Do not re-sterilize		Do not re-use