INSTRUCTIONS FOR USE

Dental Root-Canal Instruments

TS4

BEFORE USING THE PERFECT DENTAL ROOT CANAL INSTRUMENTS, PLEASE SEE THE IFU AS BELOW

FOR DENTAL USE ONLY

SINGLE-USE NON-STERILE - sterilize prior to use

0) INDICATIONS FOR USE

- Indications: The product is used for the treatment of endodontic diseases.
- Intended use: It is used for exploring, shaping, and cleaning root canal systems during dental treatment.
- Expected users: Endodontic instruments are to be used only in a clinical or hospital environment, by qualified dental professionals.
- Instruments shall be used in combination with a handpiece.

1) CONTRAINDICATIONS

It is forbidden for those who are allergic to nickel-titanium alloy.

2) COMPOSITION, SPECIFICATION AND PACKAGING

- Composition:

It consists of an operating part, a shank, and a rubber limit block. The operating part is made of nickel titanium alloy, the shank is made of copper (C3604) , and the rubber limit block is made of silicone rubber.

- Specification:

Model Code	Item Size/Taper	ISO Size/Taper	Length	Torque	Speed
/	20/.07	020 07	19mm	2.0-3.0N/cm	350-500rpm
/	15/.04	015 04	21/25/31 mm	1.0-1.5N/cm	350-500rpm
Twin Shaper	25/.02	025 02	21/25/31 mm	1.0N/cm	800-1000rpm
/	30/.04	030 04	21/25/31 mm	1.0N/cm	1000rpm
/	30/.02	030 02	21/25/31 mm	1.0N/cm	800rpm

- Packaging: 4~6pcs per blister/box (assorted/single size)

3) WARNING

Single-use products shall not be re-processed nor reused. Reusing these products increases the risk of cross-contamination and/or breakage.

4) PRECAUTIONS

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- Inspect the packaging before use and do not use the instruments if the packaging is damaged.
- Do not use the instruments after expiration date.
- Check the instrument before each use for signs of defects such as deformations (bent, unwound), breakage, corrosion, damaged cutting edges, loss of color coding or marking. With these indications the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Before using, make sure it is well connected to the contra-angle head.
- Clean the flutes frequently during instrumentation, inspecting for signs of distortion or wear, such as uneven flutes, dull spots.
- The instrument should not be completely immersed in sodium hypochlorite solution (NaoCl). Only the working part of the nickel titanium instrument in contact with the patient can be immersed in a sodium chloride solution with a concentration not exceeding 5% for no more than 5 minutes.
- Exercise caution in the apical area and around significant curvatures.
- Irrigate abundantly and frequently the canal throughout the procedure.
- Always use minimal apical pressure. Never force the files down the canal.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following :

➢ Use a new file and discard it after the canal was treated (single canal use).
➢ Use manual instead of rotary files.
➢ Use small size, flexible or/and NiTi files.
➢ Visually inspect the working part for all the defects listed in the former paragraph during use.
➢ Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

5) ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

6) STORAGE CONDITIONS

Keep the product in a dry and clean place away from light, at a relative temperature of 5°-35° and a humidity of 30%-75%.

7) STEP BY STEP INSTRUCTIONS

① Sterilize and disinfect (see section 8,Silicone rubber can be sterilized and disinfected).

② Preliminary confirmation of the working length based on image radiology judgment.
③ Use ISO 010 or ISO 015 type K file to advance with a slight thrust of 2-3mm, reaching the working length one or more times; Irrigate thoroughly with sodium hypochlorite.
④ Use Glider file 015 04 to expand the root canal opening.
⑤ Glide path preparation with shaper 030 04, Insert the 030 04 tip into the receding part of the root canal to start the root canal motor. Through long, light back and forth motions to enter the root canal by applying very low pressure until you reach the apex. If the root tip is not reached in 8 cycles, it should be stopped, washed, and prepared again after dredging with a hand file. Restart and always keep rotating and moving in the root canal. Once the apex is reached, remove the instrument to avoid excessive expansion.
⑥ Use finisher file 025 02 for deep root canal cleansing. Insert the finisher tip facing into the root canal, start the motor, and make gentle longitudinal contact of the full length of the root canal. Finishing it by 1 minute (about 60 times).
⑦ Flush the root canal and move to the next stage of treatment.

8) CLEANING AND MAINTENANCE

- Products shall be disposed according to local regulations for the safe disposal of sharp and contaminated devices.
- The product is non-sterile and needs to be cleaned, disinfected and sterilized before use. (thorough cleaning and disinfection is the prerequisite for effective sterilization) must follow the actual operation of the instrument operating instructions.
- It is recommended that products be cleaned and disinfected by mechanical procedures.
- High-temperature disinfection (disinfector/CDU) ,always ensure that the disinfector is qualified (e.g. VAH/DGHM or FDA or CE label according to DIN EN ISO 15883)
- High-temperature disinfection (93 ° C for at least 10 minutes or a value > GT. 3000) can be performed (chemical risk due to residue on the instrument)
- Proper instrument disinfection procedures, adequate cleaning cycles, use only sterile or low bacterial content (10 cfu/ml,) and endotoxin-free water (0.25 eu-/ml, such as high purity water HPW) , and regular maintenance of the sterilized instrument.
- When purchasing cleaning agents, make sure that they can be used to clean equipment if it is known that high-temperature disinfection is not possible, sanitizers that are qualified (such as VAH/DGHM or FDA certificate or CE label) and are compatible with cleaning agents must comply with the concentration ratios indicated by the detergent, sanitizer manufacturer.
- **Mechanical cleaning and disinfection procedures**:

1. Select the appropriate module for the pre-clean and place it in the sterilizer container.
2. Put the container into the sterilizer
3. Start the program
4. At the end of the program, remove the container from the sterilizer.
5. If necessary, drying it. Check the package and store in a clean place as soon as possible.

- **Manual cleaning and disinfection procedures**

Cleaning：

1. Select the appropriate module for the pre-cleaning and place it in the sterilizer container.
2. The sterilizing container shall be placed in the cleaning tank within the specified contact time. The instrument should be fully covered (with ultrasonic wash or a soft brush if necessary)
3. The container is then removed from the sink and rinsed with water (at least 3 x 1 minute)

Disinfection：

1. The sterilizing box containing the cleaning and inspection apparatus shall be put into the sterilizing tank within the specified contact time. The instrument should be fully immersed in the cleaning fluid.
2. Remove the container from the tank and rinse thoroughly with water for 5 minutes.
3. Inspect, dry and package the instrument as soon as possible.

Sterilization:

Sterilize the product using a high-pressure steam sterilizer in accordance with the prescribed methods . No other sterilization methods shall be used. High pressure steam sterilization method:

1. Vacuum fractionation (at least 3 cycles) or gravity displacement autoclave (product must be fully dried)
2. Steam sterilizers that meet the requirements of DIN EN 13060 or DIN EN 285.
3. In accordance with the provisions of ISO17665-1 certification (effective installation, Operation Qualification and product performance qualification.)

4. The maximum sterilization temperature is below 138 ° C (280°F) and the tolerance specified in ISO17665-1.
5. Put this product in a sterilization pack (or foil) and place it on a sterilization tray, or burs stand for autoclave sterilization with reference to the following terms.
6. Ensure that disinfection is effective at 121°C (250°F) for at least 20 minutes, or at 134°C (270°F) for at least 5 minutes, or at 134°C (270°F) for 18 minutes to eliminate potential prions.
7. Rapid sterilization or the use of sterilization methods for unpacked instruments shall not be allowed. In addition, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization and plasma sterilization shall not be used.
8. Do not use high pressure steam sterilizer which heats more than 200 degrees Celsius including drying process.
9. When using sterilization equipment, wash off the foreign matters.
10. Regarding use of medical cleaning agent, follow the instruction manual by its manufacturer strictly.
11. Check all instruments after cleaning or cleaning/disinfection. Defective defects should be discarded in a timely manner. Defects include: deformation, bending, thread grinding, cutting surface damage, cutting tool blunt, missing size label, has been corroded.

9) ADDITIONAL INFORMATION

- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
- Label graphics, symbols, abbreviations to explain

Symbols	Description	Symbols	Description
	Non-sterile		Do not re-use
	Consult instructions for use		Use-by-date
	Manufacturer		Date of manufacture
	Conformity European, Notified body number		Authorized representative in the European Community

	Caution		Medical device
	Batch code		Silicone
	Nickel titanium		Handle Right angle RA
	Recommended Rotation		Autoclave at the specified temperature
	Do not use if package is damaged		Keep dry

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