Dental Root-Canal Instruments Instruction manual

TF4 GOLD

Instructions for use

Before using the Perfect Dental Root Canal Instruments, please see the IFU as below

0) Instructions for use

- Indications: The product is used for the treatment of endodontic diseases
- Intended use: Medical instrument used to explore, shape, and clean the root canal system during dental treatment; this product is suitable for use in hospitals, clinics, or qualified dentists.
- Expected users: Endodontic instruments can only be used in clinical or hospital settings, following good dental practice, by qualified dental professionals such as general practitioners as well as root canal specialists (endodontists) and dental assistants.
- Instruments shall be used in combination with an endodontic motor.

1) Contraindications

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

2) Structural composition, composition, specification and recommend values of rotary and torque

- It consists of an operating part, a rod and a rubber stopper. The operating part has a working part with a cutting edge. The operating part is made of nickel-titanium alloy. The rod is made of metal material copper (C3604) with a nickel-plated gold coating. The rubber limiter The bit block is made of silicone rubber.
- Single or mixed packaging, non sterile provided.
- These instrument are heat treated to produce a golden appearance. Due to this proprietary processing, the instrument may exhibit slight bending, which is not a manufacturing defect. Although the instrument can be easily straightened with a finger file, there is no need to straighten it before use.

Once the instrument enters the root canal, the instrument will follow the shape of the root canal.

- Main Material：
  Operation part: nickel titanium alloy;
  Rod: Copper alloy (C3604)

TF4 GOLD series includes the following dental instruments:

Product Name	Specification	Operating Length	Packing (non-sterile)
TF4 GOLD	020 07	21mm	6 instruments (mixed pack)
TF4 GOLD	020 07	25mm	6 instruments (mixed pack)
TF4 GOLD	020 07	31mm	6 instruments (mixed pack)
TF4 GOLD	025 07	21mm	6 instruments (mixed pack)
TF4 GOLD	025 07	25mm	6 instruments (mixed pack)
TF4 GOLD	025 07	31mm	6 instruments (mixed pack)
TF4 GOLD	035 06	21mm	6 instruments (mixed pack)
TF4 GOLD	035 06	25mm	6 instruments (mixed pack)
TF4 GOLD	035 06	31mm	6 instruments (mixed pack)
TF4 GOLD	045 06	21mm	6 instruments (mixed pack)
TF4 GOLD	045 06	25mm	6 instruments (mixed pack)
TF4 GOLD	045 06	31mm	6 instruments (mixed pack)
TF4 GOLD	020 07	21mm	4 instruments (mixed pack)
	025 07		
	035 06		
	045 06		
TF4 GOLD	020 07	25mm	4 instruments (mixed pack)
	025 07		
	035 06		
	045 06		
TF4 GOLD	020 07	31mm	4 instruments (mixed pack)
	025 07		
	035 06		
	045 06		

- Recommend values of rotary and torque：350rpm，2-3N*cm

3) Warning

- Please strictly adhere to product sterilization, disinfection, and usage methods (see sections 7 and 8) to minimize the following risks for patients and/or users:
  - ○ Breakage of instrument
  - ○ Cross-contamination.
  - ○ Heat generation due to insufficient lubrication and irrigation
  - ○ Swallowing of working part of the instrument.
  - ○ Toxic or allergic reactions caused by processing residues

Engine Driven root canal therapy instruments are connected to active instruments for driving work. In order to reduce the risk of separation of root canal therapy instruments, they should not be used for the treatment of abnormal deformation and bending of tooth root tips.

4) Preventive measures

- 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 any instrument, make sure it is well connected to the contra-angle head.
- Check instrument and clean working part frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, dull spots. With these indications that the

devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.

- 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 in canals that divide, and/or exhibit abrupt curvatures or recurvatures.
- Irrigate abundantly and frequently the canal throughout the procedure and after each instrument used (according to good dental practices).
- Always use minimal apical pressure. Never force the files down the canal.
- When instrument does not easily progress, clean and inspect the cutting flutes, then irrigate, recapitulate with a manual file and reirrigate.
- 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 good practices:

○ 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 (this will help avoid canal transportation).

○Visually inspect the working part for all the defects listed in the former paragraph during use (i.e after each wave).

○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 limit block can be sterilized and disinfected）

② Preliminary confirmation of the working length based on image radiology judgment;

③ In the environment of sodium hypochlorite solution, use ISO 010 type K file to advance with a slight thrust of 2-3mm, and reach the working length one or more times;

④ Continue to use ISO 015 type K file to expand the root canal channel and reconfirm the working length and condition of the root canal;

⑤ Configure a dedicated dental phone setting and use product 025 07 file to perform reciprocating motion in step ③ until the working length is reached;

⑥ When the tip of the file is covered with dentin, the preparation of the root canal channel is completed;

⑦ If resistance is encountered during the shaping process, the 020 07 file should be replaced to continue preparation; If the prepared root canal channel is relatively loose and the apical dentin of the file is sparse, the 035 06 file or 045 05 file should be replaced;

⑧ Some suggestions during use.

Use a rubber barrier system to prevent swallowing, etc;

When using the instrument, it should be pushed as gently as possible.

The use of violent equipment is strictly prohibited.

The use of viscous chelating agents can relatively reduce the release of metal ions from the instrument.

The cleaning agent solution should comply with the treatment medication specifications; Do not use high concentration cleaning agents to damage the surface of the instrument.

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-aseptic 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 means:

- High-temperature disinfection (disinfector/CDU) always ensure that the disinfector is certified by an authority (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 certified by an authority (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-cleaned cleaning and place it in the sterilizer. It is forbidden to clean the loose instruments.
2. Put the sterilizer into the sterilizer
3. Start the program
4. At the end of the program, remove the sterilizer from the sterilizer.

5. After removal, if necessary, after drying. Check packaging and store cleaning in a clean place as soon as possible.

- anual cleaning and disinfection procedures

Cleaning：

1. Select the appropriate module for the pre-cleaned cleaning and place it in the sterilizer. It is forbidden to clean the loose instruments.
2. The cleaning or sterilizing box shall be placed in the cleaning tank within the specified contact time. The instrument should be fully covered (with ultrasonic support or a soft brush if necessary)
3. The instrument or sterilizer 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 trough within the further specified contact time. The instrument should be fully immersed in the cleaning fluid.
2. Remove the instrument from the tank and rinse thoroughly with water for 5 minutes.
3. Inspect, dry and package the instrument as soon as possible after removal.

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

1. Vacuum fractionation (at least 3 cycles) or gravimetric method 1(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 ISO176651 certification (effective installation, Operation Qualification and product performance qualification.)
4. 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.
5. 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, in accordance with ISO 17665 and following manufacturer-specified procedures. (If local regulations have higher requirements for sterilization, the following sterilization conditions can be used: 134°C (270°F) for 18 minutes to eliminate potential prions) .
6. Rapid sterilization or the use of sterilization methods for unpackaged instruments shall not be allowed. In addition, hot air sterilization, radiation sterilization, formaldehyde or oxirane and ion sterilization shall not be used.
7. Do not use high pressure steam sterilizer which heats more than 200 degrees Celsius including drying process. 。
8. When using sterilization equipment, wash off the foreign body. Complete sterilization。
9. Regarding use of medical cleaning agent, follow the instruction manual by its manufacturer strictly.
10. Check all instruments after cleaning or cleaning/disinfection. Defective defects should be discarded in a timely manner. Defects include: plastic

deformation, instrument bending, thread grinding, cutting surface damage, cutting tool blunt, missing size label, has been corroded

9） Attachment 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

Symbol	EN	Symbol	EN
	Handle Right angle RA		Use-by date
	Nickel titanium		Conformity European, Notified body number
	Silicone		Manufacturer
	Recommended Rotation		Authorized representative in the European Community
	Autoclave at the specified temperature		Caution
	Consult instructions for use		Date of manufacture
	Batch code		Catalogue number

【Manufacturer】Shenzhen Perfect Medical Instruments Co.,Ltd.

【Address】Room 103, Building 3, No. 2, Weiqun Road, 4th Community, Henggang Street, Longgang District, Shenzhen，518115 Guangdong,China

【Authorized representative in the European Community 】***SUNGO Europe B.V.***

【Address】Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

【FAX】0755-28540953

【TEL】0755-28540953

【Website】www.dental-perfect.com

【E-mail address】sales@dental-perfect.com

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【Useful Life】Five years

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