Dental Root-Canal Instruments Instruction manual

TH6(Hand)

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.

1) Contraindications

It is forbidden for those who are allergic to nickel.

2) Structural composition, composition and compatible equipment

- It consists of an operating part, a handle, and a rubber limit block. There is a working part with a cutting edge on the operating part. The operating part is made of nickel titanium alloy (NITI), the handle is made of plastic material (polybutylene terephthalate), and the rubber limit block is made of silicone rubber.
- Single or mixed packaging, non sterile provided.
- These instruments are generated through heat treatment with a blue appearance. Due to this proprietary treatment, the device may experience slight bending, which is not a manufacturing defect. Although the instrument can be easily straightened with fingers, there is no need to straighten it before use. Once the instrument enters the root canal, it will

follow the shape of the root canal.

- Main Material：

Operation part: nickel titanium alloy;
Handle: Plastic material (polybutylene terephthalate)

TH6(Hand) includes the following dental instruments:

Product Name	Specification	Operating Length	Packing (non-sterile)
TH6	019 04	19mm	6 instruments (single pack)
TH6	018 02	21mm	6 instruments (single pack)
TH6	018 02	25mm	6 instruments (single pack)
TH6	018 02	31mm	6 instruments (single pack)
TH6	020 04	21mm	6 instruments (single pack)
TH6	020 04	25mm	6 instruments (single pack)
TH6	020 04	31mm	6 instruments (single pack)
TH6	020 07	21mm	6 instruments (single pack)
TH6	020 07	25mm	6 instruments (single pack)
TH6	020 07	31mm	6 instruments (single pack)
TH6	025 08	21mm	6 instruments (single pack)
TH6	025 08	25mm	6 instruments (single pack)
TH6	025 08	31mm	6 instruments (single pack)
TH6	030 09	21mm	6 instruments (single pack)
TH6	030 09	25mm	6 instruments (single pack)
TH6	030 09	31mm	6 instruments (single pack)
TH6	040 06	21mm	6 instruments (single pack)
TH6	040 06	25mm	6 instruments (single pack)
TH6	040 06	31mm	6 instruments (single pack)
TH6	050 05	21mm	6 instruments (single pack)
TH6	050 05	25mm	6 instruments (single pack)
TH6	050 05	31mm	6 instruments (single pack)
TH6	019 04	21mm,19mm	6 instruments (mixed pack)
	018 02		
	020 04		
	020 07		
	025 08		
	030 09		
TH6	019 04	25mm,19mm	6 instruments (mixed pack)
	018 02		
	020 04		
	020 07		
	025 08		
	030 09		

TH6	019 04	31mm,19mm	6 instruments (mixed pack)
	018 02		
	020 04		
	020 07		
	025 08		
	030 09		

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

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, please ensure that it comes with an anti drop rope.

- 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, reaching 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 Use product 018 02 to clear the root canal channel using the action of step ③ until the working length is reached (if necessary, use product 019 04 file to expand the root canal channel opening).

⑥ Use products 020 04&020 07 to shape the root canal channel until the working length is reached.

⑦ Check and use ISO 020 type K file to enter the root canal channel to reach the working length. If the compactness is appropriate, complete the shaping of the root canal channel; If it is loose or not tight, it is recommended to continue using a larger model of this product to shape the root canal channel. Use it sequentially from small to large, and check with a corresponding size K file until the shaping of the root canal channel is completed.

⑧ Here are some suggestions for use:

Use a rubber barrier system to prevent swallowing, etc;

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

Devices strictly prohibited from violent use;

During the use of the instrument, it should be thoroughly and repeatedly flushed to prevent blockage.

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, and do not use high concentrations of cleaning agents to

damage the surface of the device...

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

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【Useful Life】Five years

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