

Instructions for Dental Explorer

Read the instructions carefully before use and keep them properly for future reference

1. Product name

Dental Explorer

2. Product structure and composition

The product is composed of a handheld part and a slender working end. The working end has different shapes and surfaces depending on its purpose.

3. Product model

TFRK-ME、 TFRK-GPR



TFRK-ME



TFRK-GPR

4.Intended Use

Used for exploration or treatment of tooth surface, tooth body, pulp, and surrounding tissues.

5. Product performance

- 1 The external surface of the instrument is smooth and free of burrs.
- 2 Passive products.
- 3 Non-sterile supply.

6. Production date

See product packaging label.

7. Service life

10 years.

8. Contraindications

Patients with heart disease, pregnant women, and young children should use it with caution.

9. Precautions

- 1 The product is only used by professional doctors or technicians.
- 2 After sterilization of the product, avoid contacting it with other equipment to avoid cross infection.
- 3 The equipment should be avoided from severe impact, such as falling from a height, which may cause damage to the equipment.

10. Product use method

- 1 This product is used as disposable.
- 2 This device is only applicable to its corresponding scope of application, and is not used for other purposes, which will damage the device or have poor effect.
- 3 It should be operated and used by professionals. Use this device carefully.
- 4 Before using new instruments, they must be cleaned, disinfected and sterilized.
- 5 The device has movable components, which should be carefully inspected before use to ensure good operation of the device.

11.Storage conditions

- 1 The equipment should be handled with care, kept away from the shake source, installed and stored in a cool, dry and ventilated place.
- 2 Don't store it together with articles that are poisonous, caustic, inflammable or explosive.
- 3 The product should be stored in the environment with relative humidity no more than 10%~93%,atmospheric pressure 70kPa~106kPa,temperature between -20℃ ~+55℃ .

12.Product maintenance

The device should avoid contact with hydrogen peroxide, sodium hypochlorite and other solutions. If there is contact, please wash it with clean water in time to avoid damage to the device.

13.Cleaning and Sterilization

Warnings:

This device shall not be exposed to high temperature above 138°C.

1.Automationed cleaning

Automatic cleaning must be performed with an automatic cleaning instrument conforming to EN ISO 15883. The cleaning requirements are as follows:

- (1) Remove the handle long rod, handle short rod, lock nut, and needle core, and rinse away the dirt on the surface of them with pure water (or distilled water/deionized water)
- (2) Dry the product with a clean, soft cloth and place them in a clean tray.
- (3) Carefully place the products into the washer-disinfector .
- (4) Start the program of the washer:
- (5) 3 min pre-washing with cold water(<40°C);
- (6) Clear
- (7) Wash with neodisher MediZym (Dr. Weigert) diluted with deionized water (<45°C) for 5 minutes;
- Cleaning Agent: neodisher MediZym
- (8) Clear
- (9) Rinse with cold deionized water for 1 minuter (<40°C);
- (10) Clear
- (11) Rinse with cold deionized water for 1 minuter (<40°C);
- (12) Clear
- (13) Drying 20 minutes

Notes :

(1) If the automatic cleaning equipment has no automatic drying function, it is necessary to use a clean absorbent soft cloth to wipe the residual water stains on the surface of the sample.

Methods :

·Spread a clean white paper (white cloth) on the flat table, point the products against the white paper (white cloth), and then dry the products with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

·It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80°C~120°C and the time should be 15~40 minutes.

(2) Visual inspection:

Before packaging and auto sterilization, make sure that the product has been cleaned according to manufacturer's instruction. Visually check the integrity and cleanliness of the cartridge holder:

—If there is still visible stain on the product after cleaning, the entire cleaning process must be repeated.

—If the appearance of the product is obviously damaged, crushed, fallen off, corroded or bent, it must be scrapped and not allowed to continue to be used.

2.Sterilization

(1) Pack the product in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

(2) Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

(3) The sterilization program should include the following key parameters:

Sterilization time :5 minutes

Pressure:2.0 bar ~ 2.3 bars

Temperature:134°C

Drying time :20 minutes.

Note :

(1) The product that has been sterilized should be placed in a sterilization packaging, and then taken out before use. The packaging material shall meet the requirements of EN ISO 11607.

(2) After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

(3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.

(4) Please use the recommended sterilization procedures . It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

14.Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

c) Before use, pay attention to check the packaging, if it is damaged, please rinse and sterilize before use.

15.Transportation

1. Excessive shock and vibration should be prevented during transportation, and handled with care;
2. Transport should not be mixed with dangerous goods.
3. Avoid exposure to sun or rain or snow during transportation.

16.General safety instructions

Before use, check that the instrument has not been damaged and that all components are present. No modifications to the instrument may be made without the express permission of the company.

17.Instrument hygiene

The instrument is not delivered sterile. Before use, the instrument must be sterilized. The instrument is for single use only.

18.Disposal

The relevant statutory provisions regarding the disposal of medical waste apply.

19.Symbol instruction

	Manufacturer
	Date of manufacture
	Can be autoclaved
	Follow instructions for use
	Authorised Representative in the EUROPEAN COMMUNITY
	CE marked
	Medical Device
	Do not reuse

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ZMN-SM-842 V1.1 20230728