SHENZHEN ROGIN MEDICAL CO., LTD
Address:5th Floor, Block I, Jinchangda Science Park, Shangwei Industry District, Shangkeng community, Guanhu Street, Longhua District, Shenzhen, China

受控文件

Instructions for use
Of
Rotary Use Retreatment Files

Doc. No.: LJYL-IFU-B035

Version: A1

Effective: 2023-05-15

Before using the products, please see the instruction manual as indicated below.

1. Brief of the product

The ROGIN Retreatment Files is one type of Dental root canal instrument designed for removing gutta percha and fillings in root canal by installing on the contra angle of Endo Motor to doing the movements of lifting and vertical reciprocation.

It is a taper instrument with taper more than 2% taper, which is type 4 classification base on ISO3630-1:2019;

It is non sterile instruments.

2. Intended Use

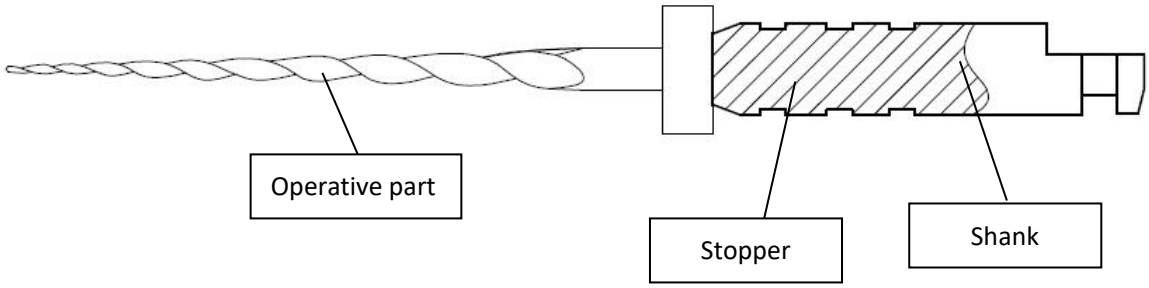
The Dental Root Canal Instruments is designed to explore, shape, clean and/or help filling a root canal system.

3. Product Structure and materials

The ROGIN Retreatment Files is composed of operative part, stoppers and shank.

The main Materials:

1) Operative part: Nickel Titanium
2) Shank: Brass C3604
3) Stoppers: Colorless translucent rubber (CAN19-259705.001)



4. Before Using

<Warnings>

3.1 Only skilled dentists are allowed to use.

3.2 Be sure to sterilize this product for each use.

3.3 Do not use this product except for the dental service and treatment. Use it in accordance with the intended use.

<Contraindications and prohibitions>

Do not use this product for a patient who indicates sensitization and allergic reaction.

Re-Processing (base on ISO 17664: 2017)

Our Dental Root Canal Instruments are single use and not approved for re-use.

5. Specifications and Method of Use

5.1 The Specification of ROGIN Retreatment Files as the below table (based on ISO 3630-1&ISO3630-5):

Size	Working Length (mm)	Tip Diameter (mm)	Tape (%)	Number of grooves
D1	16	0.19	9	I
D2	18	0.17	8	II
D3	22	0.20	7	III

5.2 The Retreatment Files is use to remove the gum tip inside the root canal after failed root canal treatment

5.3 Choose the most appropriative size for each case and follow the general method.

5.4 **Recommended rotation speed: 150-350 rpm/min, Torque: 2.0- 2.5N.cm.**

55 This ROGIN Retreatment Files is under the provisions of ISO 3630 performance test, products' durability for twisting and bending must exceed specified value of our standard

6. Precautions for use:

6.1 To prevent infection, pls clean and disinfect the product (pls see item 7) and make sure sterilization is completed before using.

6.2 Choose the most appropriative type for each case and follow the general method.

6.3 Before using, make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks.

6.4 If the head of product is thin, long or large, there are possibilities for breaking or twisting. Because of this, be sure to avoid using unreasonable angle and excessive pressure.

6.5 Wear rubber dam etc. to avoid accidental ingestion and falling.

6.6 Do not use this instrument for any purposes except for listed applications above.

6.7 Only for use by dentists.

6.8 This product should be treated as medical waste when disposed.

6.9 Dispose the product if damaged or contaminated.

6.10 After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.

6.11Set the product to a stand when cleaned by ultrasonic cleaner to avoid deterioration of cutting part.

6.12Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.

6.13This product has possibility that be corrosive if sunk into NaOC1, EDTA and etc. for a long time.

7. Cleaning and Disinfection (base on ISO 17664: 2017)

7.1General Recommendation

7.1.1 Please use cleaning agents suitable for cleaning surgical instruments, rubber, medical plastics, instruments and other medical instruments, such as multi-enzyme cleaning agents. When

using, please strictly abide by the manufacturer's regulations on the concentration, temperature, action time and shelf life of the solution used. Do not use hydrogen peroxide (H2O2) solution.

7.1.2 For your own safety, please wear personal protective equipment (gloves, glasses, masks).

7.1.3 The user should be responsible for the sterilization or disinfection of the product in the first cycle and each subsequent use, as well as the use of damaged or dirty equipment after sterilization.

7.1.4 In the final rinsing step, deionized water must be used regardless of whether an automatic washer sterilizer or manual cleaning method is used. Tap water can also be used for other rinsing steps.

7.1.5 Only immerse the operative part of the instrument in contact with the patient into the NaOCl solution concentrate with a concentration not exceeding 5%.

7.1.6 Before or during disinfection or cleaning, avoid equipment drying out. Dry biological materials may be difficult to remove.

7.1.7 Only use the appropriate support of the device for post-processing.

7.1.8 Do not use labeling systems or identification marks directly on the device.

7.1.9 Only use washer-disinfectors approved in accordance with EN ISO 15883 and regularly maintained and verified.

7.2 Operation Steps

7.2.1 **Disassembling**: Remove the stopper from the instrument and dispose of it

7.2.2 **Rinsing:** Rinse extensively (at least 1 minute) under flowing deionized water (ambient temperature). While rinsing, use a soft brush (made of nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.

7.2.3 Cleaning and Disinfection

7.2.3.1 Manual Cleaning assisted by an ultrasonic device:

7.2.3.1.1 Manual cleaning with ultrasonic equipment

7.2.3.1.2 Place the instrument in a kit, stand or container (made of stainless steel, polypropylene or titanium).

7.2.3.1.3 Immerse in a detergent solution(for example, Metrex EmPowder concentration 1:128) with cleaning properties, if appropriate, soak for at least 15 minutes with the aid of ultrasonic equipment.

7.2.3.1.4 Flushing: Perform a large amount of flushing (at least 1 minute) under flowing deionized water temperature 20°C ~ 40°C.

7.2.3.1.5 Drying: Dry with a disposable non-woven fabric or hot air dryer not exceeding 110°C.

7.2.3.2 Automated Cleaning using a cleaning and disinfecting device

7.2.3.2.1 Place the instrument in a kit, stand or container (made of stainless steel or titanium).

7.2.3.2.2 Perform the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 ~ 1:512) for at least 5 minutes in the washer-disinfector with temperature 20°C ~ 40°C.

7.2.3.3 Disinfection using a washer-disinfector device

7.2.3.3.1 Place the instrument in a kit, stand or container (made of stainless steel or titanium).

7.2.3.3.2 Perform the defined cycle with mild neutral enzyme cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector with temperature >90°C, A_0 >3000.

Note:

1) Discard any instruments with obvious defects (broken, bent, etc.).

2) When the instruments are placed in the cleaning kit, support or container, avoid any contact with each other.

3) Follow the instructions and concentration provided by the detergent solution manufacturer (see also general recommendations).

4) Follow the instructions of the washer-disinfector and verify the success criteria after each cycle is reached according to the manufacturer's instructions.

5) The final rinse step should use deionized water. For other steps, follow the water quality defined by the manufacturer. Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts.

7.2.4 **Rinsing:** Abundant rinsing (at least 1 min) under running water (ambient temperature).

1) Use deionized water for rinsing.
2) If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.

7.2.5 **Drying:** Devices should be thoroughly dried before inspection and packaging.

1) Dry on a single use non-woven cloth, or with a hot air drier at not more than 110°C.
2) Devices should be dried until visual traces of moisture are eliminated.
3) Particular attention has to be paid to effectively dry joints or cavities within a device.

7.2.6 Inspection:

7.2.6.1.1 Inspect the devices functionality.

7.2.6.1.2 Inspect devices and sort out those with defects.

1) Dirty devices must be cleaned again.
2) Do not re-use silicon stops.
3) Discard devices, which show any defect

7.2.7 **Packing:** Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilization pouches”.

1) Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers.

2) For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.

3) Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated.

4) Check the validity period of the pouch given by the pouch manufacturer to

determine the shelf life.

7.2.8 Sterilization:

7.2.8.1 Steam sterilization at 132°C / 273°F during 4 min is recommended for these devices, for the purpose of de- activating potential prions.

7.2.8.2 The instruments and posts must be sterilized according to the packaging labelling.

7.2.8.3 Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer.

7.2.8.4 Use only steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer), EN 285 (full size sterilizer).

7.2.8.5 Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min

7.2.8.6 Respect the maintenance procedure of the sterilizer given by the sterilizer manufacturer.

7.2.8.7 Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters).

7.2.8.8 Store traceability records and define shelf-life according to packaging manufacturer guidelines.

7.2.8.9 Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions.

7.2.9 Storage

Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.

1) Sterility cannot be guaranteed if packaging is open, damaged or wet.

2) Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).

8. Transportation

8.1 To prevent damage to the medical device during transit, use a specific racks, trays or rigid containers may be recommended.

8.2 When the package was broken, then it is non-sterilize, must be cleaned, disinfected and sterilized before using.

9. Storages and duration of use

9.1 Avoid storing at high temperature, humidity and direct sunlight. Keep liquids away. Store it at room temperature.

9.2 Do not damage or make a pinhole to packaging materials.

9.3 The product is subject to be improved without previous notice. Enforce the first-in first-out method for stock management.

9.4 Do not keep under germicidal lamp to avoid deterioration.

9.5 The shelf time of root canal files are 5 years.

10. Disposal

For proper disposal, always observe national laws and recommendations of the authorities.

11. Packaging

11.1Minimum packaging unit: 6pcs/package in aluminum foil box.

11.2Assortment: 2pcs from each size in one package

3. Explanation of related symbols

Symbols	Explanation
	Medical device
	CE notify body code
	For Dental Use Only
	Do not reuse
	Material of the working part: Nickel Titanium
	Recommended rotation speed
	Recommended torque for use
	Batch code
	Non-Sterile
	Catalogue Number
	Expired Date
	Consult instructions for use
	Authorized representative in the European Community

	Manufacturer
	Can be sterilized at the specified temperature
	Assortment
	6pcs/pack

<Legal manufacturer>

Shenzhen Rogin Medical Co., Ltd

Address:5th Floor, Block I, Jinchangda Science Park, Shangwei Industry District, Shangkeng community, Guanhu Street, Longhua District, Shenzhen, China

Tel.: 86 755 26758272 / Fax.: 86 755 26758272

www.rogindental.com

< EU representative>

CE 0197

EC REP MedNet EC-REP GmbH
Borkstrasse10,48163 Muenster,Germany

※ Always keep this document near at hand. In case of loss, please contact dental department of the manufacturer for a copy.

※ The specifications, structures and materials are subject to be changed without previous notices for the demands of improvement.

※ The contents of this instruction manual are subject to be revised without previous notices.