SHENZHEN ROGIN MEDICAL CO., LTD

Instructions For Use
Of
Manual Root Canal Files (Stainless Steel)

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

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1. Indications for Use

- The ROGIN Manual Root Canal Files (Stainless Steel) are indicated for treatment of endodontic disease.
- Intended Use: The product is hand-held operated instruments intended for root canal preparation (shaping, debridement of the root canal). It is standard instrument with 2% taper, type 1 classification base on ISO 3630-1.
- It is reusable and non-sterile instruments.
- For Dental Use Only.

2. Content, Composition and Compatible Devices

The S.S. Manual Root Canal Files are composed of handle and operative part, it divides to different models according to different design in the shape of the cross-section, the pitch of thread, and the length of the working part;

The main Materials:

1) Operative part: Stainless Steel
2) Handle: PBT + 10% glass fiber
3) Stoppers: silicone rubber

3. Safety Notes

<Warnings>

- Strictly follow this Instruction for Use and the General Processing Instructions For Endodontic Products (see section 8) to minimize following risks to the device, the patient and/or the user:
  - ○ 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.

<Contraindications and prohibitions>

None Known

Pregnant or breastfeeding women should use this product under the guidance of a doctor, weighing the benefits against the risks and avoiding unnecessary procedures.

<Adverse Reactions>

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

4. Re-Processing

4.1 The ROGIN Manual Root Canal Files are reusable instruments, the maximum number of processing cycles of the ROGIN Manual Root Canal Files is 8 (number of processing cycles validated without affecting the functionality and safety of the products).

Pls follow the processing instructions for the disinfection, cleaning and sterilization steps before each reuse as Item 7 of this IFU.

4.2 Do not re-use silicone stoppers. Remove and discard silicone stoppers after each use.

4.3 LIMITATION ON RE-USE

• The products shall not be processed more than the number of maximum cycles indicated in the table in section 4) STEP-BY-STEP INSTRUCTIONS. It is the responsibility of the user to monitor the number of processing cycles. Meanwhile re-use is permitted only when the product is defect free and following a visual inspection (see item below). Since certain applications may cause the instruments to prematurely reach the end of their useful life the “Max number of processing cycles” will not always be reached (e.g. when shaping an extremely curved root canal with a file).

• In any case inspect the products before re-use, and discard them in case of defects. These include but not limited to the following:

- Plastic deformation (bent, unwound, distorsion, sign of twisting, elongation, uneven flutes);
- Breakage;
- Loss of colour coding or marking;
- Bent instrument;
- Untwisted threads;
- Damaged cutting surfaces and edges;
- Dull cutting blades;
- Missing size marking;
- Corrosion (e.g. dull spots);
- Wear.

• 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 Manual Root Canal Files.
- Use small size, flexible files (this will help avoid canal transportation).
- Visually inspect the active 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. Specifications and Method of Use

5.1 The ENDO Manual Root Canal Files are divides to different models base on different design in the shape of the cross-section, the pitch of thread, and the length of the working part as the following:

Model Name	Specification	working length /working part (mm)	Tip Diameter (mm)	Colour of handle	Taper (%)
Stainless Steel K-Files	#06	21/16 25/16 28/16 31/17 60/30 80/30 120/30	0.06	Pink	2
	#08		0.08	Grey	2
	#10		0.10	Purple	2
	#15		0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2
	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2
	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2
Stainless Steel H-Files	#06	21/16 25/16 28/16 31/17 60/30 80/30 120/30	0.06	Pink	2
	#08		0.08	Grey	2
	#10		0.10	Purple	2
	#15		0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2
	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2

	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2
Stainless Steel Reamers	#06	21/16 25/16 28/16 31/17 60/30 80/30 120/30	0.06	Pink	2
	#08		0.08	Grey	2
	#10		0.10	Purple	2
	#15		0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2
	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2
	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2
Stainless Steel C+ Files	#06	21/16 25/16	0.06	Pink	2
	#08		0.08	Grey	2
	#10		0.10	Brown	2
	#12.5		0.125	Red	2
	#15		0.20	White	2
Stainless Steel C PRO Files	#06	21/16 25/16	0.06	Pink	2
	#08		0.08	Grey	2
	#10		0.10	Brown	2
	#12.5		0.125	Red	2
	#15		0.20	White	2
Flexile files	#15	21/25/31mm	0.15	White	2
	#20		0.20	Yellow	2

	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
PF Files	#08	21/17 25/17 31/17	0.08	Grey	2
	#10		0.10	Purple	2
	#12		0.12	Brown	2
	#15		0.15	Yellow	2
Patency Finder	#08	21/17 25/17 31/17	0.08	Grey	2
	#10		0.10	Purple	2
	#12		0.12	Brown	2
	#15		0.15	Yellow	2
Stainless Steel Vet Endo Manual K Files	#15	31/60/80/120mm	0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2
	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2
	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2
Stainless Steel Vet Endo Manual H Files	#15	31/60/80/120mm	0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2

	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2
	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2
Stainless Steel Vet Endo Manual Reamers	#15	31/60/80/120mm	0.15	White	2
	#20		0.20	Yellow	2
	#25		0.25	Red	2
	#30		0.30	Blue	2
	#35		0.35	Green	2
	#40		0.40	Black	2
	#45		0.45	White	2
	#50		0.50	Yellow	2
	#55		0.55	Red	2
	#60		0.60	Blue	2
	#70		0.70	Green	2
	#80		0.80	Black	2
	#90		0.90	White	2
	#100		1.00	Yellow	2
	#110		1.10	Red	2
	#120		1.20	Blue	2
	#130		1.30	Green	2
	#140		1.40	Black	2

5.2 Method of Use

- Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root canal.
- Create straight-line access to the canal orifice(s) with emphasis on flaring, flattening, and finishing the internal axial walls.
- Irrigate abundantly and frequently after each instrument used (according to good dental practices).
- Passively scout the coronal 2/3 with hand files ISO 010 and ISO 015, in the presence of a viscous chelator.
- Gently work these instruments until a smooth, reproducible glide path is confirmed. Alternatively, mechanized glide path files (such as ROGIN Entrance Files or ROGIN pro-path Files) may be used after an ISO 010 hand file.
- Choose the most appropriative model of Manual Root Canal Files according to situation of each case

and follow the general method.

- Use dedicated paper points to dry and dedicated gutta-percha points to obturate the root canals.

6. Precautions for use

- Use a rubber dam system during the endodontic procedure.
- 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.
- 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.
- Instruments should not be fully immersed in a sodium hypochlorite solution (NaOCl). Only the working part of the instrument, which is in contact with the patient should be immersed in a NaOCl solution concentrate at NOT more than 5%.
- 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 small size, flexible 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

7. Cleaning, Disinfection and Sterilization Method

7.1 General 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 of Cleaning, Disinfection and Sterilization

Step-by-Step instructions for processing prior to use/reuse as below table:

Step	Processing instructions
Preparation at the Point of Use	Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Transportation	Safely store the device in a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination and Cleaning	The devices must be reprocessed in a disassembled state, as far as possible. Before cleaning, disassemble each instrument to the smallest removable unit according to the instructions. For lumen instrument, ensure that the lumen of device is not clogged. The patency of the lumen can be tested by injecting water into the lumen.
Pre-Cleaning	Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution. Clean the surfaces with a soft bristle brush.
Cleaning	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better reproducibility and standardization, and in personnel protection. Automated Cleaning Use a washer-disinfector meeting the requirements of the ISO 15883 series. The instruments are placed on the cleaning rack of the WD. A cleaning tray may be used to avoid that the small device is washed away

	and lost during cleaning. The lumen of device is connected to the flushing port of the WD. The devices in the washer-disinfector are arranged in such a way that there is no rinsing shadow and the water drains off quickly. Note: Demineralised water should be used for the automated cleaning process. Water quality refer to EN 285. Start the program: • 4 min pre-washing with cold water (<40°C); • emptying • 5 min washing with a mild alkaline cleaner at 55°C • emptying • 3 min rinsing with warm water (>40°C); • emptying • 5 min intermediate rinsing with warm water (>40°C) • Emptying The automated cleaning processes have been validated by using 0.5% *neodisher MediClean* forte (Dr. Weigert) in the washer/disinfector of *BeliMed* WD425. Note Demineralised water should be used for the automated cleaning process. Water quality refer to EN 285. Note Acc. to ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see ISO 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at ≥ 93 °C due to the normally tolerable temperature fluctuations in WD.
Drying	Drying the instrument through drying cycle of washer/disinfector. If needed, (additional) manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.
Functional Testing, Maintenance	Visual inspection for cleanliness of the products and reassembling, if required. All instruments should be checked again for dryness. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. - Check that the product has no dents, cracks, deformations, scratches, etc.; - Check all markings on the product for clear visibility. Discard and replace any non-conform devices as necessary. Do not use the device with following defects: material deformation, cracks on the product, rust, brittle or other change in the material, etc. Before packaging and sterilization, make sure that these devices have been tested and maintained acc. to manufacturer's instruction.

Packaging	Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to ISO 11607. Make sure that the packaging material is suitable for steam sterilization.
Sterilization	Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respective country requirements. Following sterilization parameters are commonly used: 132°C, 4 min or 134°C, 5 min (standard program in EU). Drying time: For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After Sterilization a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. c. Check that the sterilization wraps or pouches are not damaged.
Storage	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

8. Transportation

- The product shall be stored and transported in an environment with temperature ranging from 0℃ to 40℃ and relative humidity 10 ~ 85 %RH, away from high temperature, high humidity, direct sunlight and extreme temperatures, with intact packaging.
- 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 Keep products in a dry and clean environment, away from sources of moisture and direct sunlight.

9.2 Do not use after the expiration date indicated on the label.

10. Safe disposal of the device

Products shall be disposed according to local regulations for the safe disposal of sharp and contaminated devices.

11. Serious incident reporting

Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.

12. Explanation of related symbols

Symbols	Explanation
MD	Medical device
For Dental Use Only	For Dental Use Only
SSt	Material of the operative part: Stainless Steel
LOT	Batch code
NON STERILE	Non-Sterile
1	Single patient multiple use
8	Maximum reprocessing cycles times
REF	Catalogue Number
UDI	Unique device identifier
	Expired Date
eIFU indicator	Consult electronic instructions for use
EC REP	Authorized representative in the European Country
	Manufacturer
134°C	Can be sterilized at the specified temperature
6pcs/pack	6pcs per one minimum package
CE 0197	Notify Body

13. WARRANTY AND LIMITED REMEDY / LIMITATION OF LIABILITY

Disclaimer: The instructions for use have been validated by ROGIN. Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for endodontic treatment and/or

processing when applicable. ROGIN accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the instructions for use set forth above. The user shall observe safe and lawful practices including, but not limited to, those set forth in this document.

<Legal manufacturer>

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CE 0197

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Revision History

Rev	Item	Description	Release date
A0	/	New Issue	2023-05-23
A1	3<Contraindications and prohibitions>	To add contraindications for special patient.	2026-03-18
	8	Add condition of transportation and storage	
	7.2	Delete the duplicate words “and Transportation” in step “Preparation at the Point of Use”.	
		Add detailed cleaning parameters and recommended cleaning agent to the processing instruction “Cleaning”.	