ORIGINAL

Instructions For Use

Barbed Broaches

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

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1. Indications for Use

- Barbed Broaches are are indicated for treatment of endodontic disease.
- Barbed Broaches are hand-held operated instruments use for removing the pulp tissue during root canal treatment. The device is classification type 1 of auxiliary instrument of Endodontic Instruments base on ISO3630-4.
- It is Single-Use and non-sterile instruments.
- For Dental Use Only.

2. Product Structure and materials

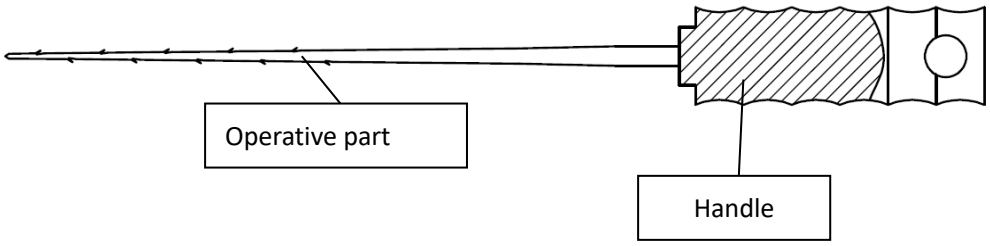
There are two types of Barbed Broaches: Short Barbed Broaches and Long Barbed Broaches:

2.1 **Short Barbed Broaches**: It is composed of handle and operative part.

The main Materials:

1) Operative part: Stainless steel

2) Handle: PBT + 10% glass fiber



2.2 **Long Barbed Broaches**: The Long Barbed Broaches is 52mm length and its handle and operative part are in one-piece:

The main Materials:

1) Operative part: Stainless steel



2.3 **Square Broaches**: The Square Broaches is 52mm length and its handle and operative part are in one-piece:

The main Materials:

1) Operative part: Stainless steel



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

The ROGIN Barbed Broaches are single, pls follow the processing instructions for the disinfection, cleaning and sterilization steps before use as Item 7 of this IFU.

5. Specifications and Method of Use

5.1 The Specification of Short Barbed Broaches as the below table:

Name	Size	Working Length (mm)	Tip Diameter (mm)	Taper	Color of handle
Short Barbed Broaches	#0	21mm 25mm	0.10	2%	Purple
	#1		0.15	2%	White
	#2		0.20	2%	Yellow
	#3		0.25	2%	Red
	#4		0.30	2%	Blue
	#5		0.35	2%	Green

	#6		0.40	2%	Black
	#15		0.15	2%	Red
	#20		0.20	2%	Blue
	#25		0.25	2%	Brown
	#30		0.30	2%	Black
	#35		0.35	2%	Sliver
	#40		0.40	2%	Yellow
	#45		0.15	2%	Red
	#50		0.20	2%	Blue
	#55		0.25	2%	Brown
	#60		0.30	2%	Black
	#70		0.35	2%	Sliver
	#80		0.40	2%	Yellow
Long Barbed Broaches	#0	52mm	0.10	2%	/
	#00		0.13	2%	/
	#000		018	2%	/
Square Broaches	#0	52mm	0.10	2%	/
	#00		0.13	2%	/
	#000		018	2%	/

5.2 According to its intended use, the dentists can choose the most appropriative type for each case and follow the general method.

5.3 This Barbed Broaches 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

- 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

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 Keep products in a dry and clean environment, away from sources of moisture and direct sunlight.

9.2 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

11.1 Minimum packaging unit: 10pcs/package in aluminum foil box.

11.2 Assortment: 1pcs from each size in one package

12. Explanation of related symbols

Symbols	Explanation
	Medical device
	For Dental Use Only
	Material of the operative part
	Batch code
	Unique device identifier
	Identification symbols of barbed broaches
	Non-Sterile

	Do not reuse
	Catalogue Number
	Expired Date
	Consult electronic instructions for use
	Authorized representative in the European Community
	Manufacturer
	Notify Body
	Can be sterilized at the specified temperature
	Assortment
	10pcs/pack

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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A0	/	New Issue	2023-05-23
A1	3<Contraindications and prohibitions>	To add contraindications for special patient.	2026-03-18