

Patterson® NiTi Files

FOR DENTAL USE ONLY

FOR PROFESSIONAL USE ONLY

SINGLE USE – REPROCESSING PROHIBITED / LIABLE FOR REPROCESSING

STERILE – STERILIZED BY RADIATION / NON-STERILE – STERILIZE BEFORE FIRST USE

INSTRUCTIONS FOR USE

SINGLE USE STERILE ENDODONTIC INSTRUMENTS

REUSABLE NON-STERILE ENDODONTIC INSTRUMENTS

0) INDICATIONS FOR USE

- Intraoral rotary dental devices intended to be attached to dental handpieces for various dental and endodontic procedures.

1) CONTRAINDICATIONS

None.

2) CONTENT, COMPOSITION AND COMPATIBLE DEVICES

Patterson® NiTi Files instruments are made of three main components: the working part made of a nickel titanium alloy, a colored silicone stopper and a plated brass shank with colored rings.

The Patterson® NiTi Files range comprises the following endodontic instruments:

Product	ISO XXX YYY XXX-ISO size YYY-taper size	Available lengths	Packaging and content
Patterson® NiTi Files .04	ISO 015 004 ISO 020 004 ISO 025 004 ISO 030 004 ISO 035 004 ISO 040 004 ISO 045 004 ISO 060 004	21/25/30 mm	Plastic box with 6 instruments (nonsterile)
Patterson® NiTi Files .06	ISO 015 006 ISO 020 006 ISO 025 006 ISO 030 006 ISO 035 006 ISO 040 006	21/25/30 mm	Plastic box with 6 instruments (nonsterile)

- Torque control devices ensure optimal usage.
- Use with endodontic motors in a constant rotation at a speed of 150 - 350 rpm.
- Set torque at:

File Size	Torque [Ncm]	Speed [rpm]
Patterson® NiTi Files ISO 015 004 Patterson® NiTi Files ISO 020 004 Patterson® NiTi Files ISO 025 004 Patterson® NiTi Files ISO 030 004	0.6-1	250
Patterson® NiTi Files ISO 035 004 Patterson® NiTi Files ISO 040 004	1-1.5	
Patterson® NiTi Files ISO 045 004 Patterson® NiTi Files ISO 030 006 Patterson® NiTi Files ISO 035 006 Patterson® NiTi Files ISO 040 006	2-3	
Patterson® NiTi Files ISO 060 004	3-4	
Patterson® NiTi Files ISO 015 006 Patterson® NiTi Files ISO 020 006 Patterson® NiTi Files ISO 025 006	1.5-2	

- Lubricants such as NaOCl, EDTA, ProLube, Glyde™ shall be used.
- The use of radiographs in combination with an apex locator and a tool for adjusting the silicone stopper to the correct working length is the appropriate method of working length determination.

3) WARNINGS

- Strictly follow this Instruction for Use and the Processing of Patterson® Products (see section 8) to minimize the 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.
- Similar to all machine-driven root canal instruments, Patterson® NiTi File instruments should not be used in a root canal with an abrupt apical curvature due to heightened risk of separation. In this case, pre-curved hand files should be used in the apical region.

4) PRECAUTIONS

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- 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 fulfill the intended use with the required safety level, instruments should be discarded.
- Before using any instrument, make sure it is well connected to the contra angle head.
- 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 fulfill 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 NiTi 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 manual instead of rotary files.
 - Use small size, flexible and/or 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 products in a dry and clean environment, away from sources of moisture and direct sunlight.

7) STEP BY STEP INSTRUCTIONS

- 1) Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root canal.
- 2) Create straight-line access to the canal orifice(s) with emphasis on flaring, flattening, and finishing the internal axial walls.
- 3) Irrigate abundantly and frequently after each instrument used (according to good dental practices).

Patterson® NiTi File sequence for narrow canals:

Step	Instrument	ISO Color	Number of rings on handle
Crown-Down Sequence	Patterson® NiTi Files O.S.3 (ISO 040 006)	Red	3
	Patterson® NiTi Files O.S.2 (ISO 030 006)	Yellow	3
	Patterson® NiTi Files ISO 025 006	Red	2
	Patterson® NiTi Files ISO 020 006	Yellow	2
	Patterson® NiTi Files ISO 025 004	Red	1
	K-File 015	White	N/A
	Patterson® NiTi Files ISO 020 004	Yellow	1
Apical preparation	Patterson® NiTi Files ISO 020 004	Yellow	1
	Patterson® NiTi Files ISO 025 004	Red	1
Flaring	Patterson® NiTi Files ISO 020 006	Yellow	2

- 4) Start using every instrument for approx. 5-10 seconds and never force a NiTi file into the canal.
- 5) When progression becomes difficult, withdraw the instrument and go on to the next smaller file size.
- 6) To determine the exact working length, use a K-File as a depth gauge after the first NiTi file has reached the minimum estimated working length less 3 mm (ex.: 21-3 =18 mm).
- 7) The Crown-Down Sequence will be continued until the exact working length is reached.
- 8) Continue Crown-Down Sequence up until the foramen, using an apex locator as reference.
- 9) Continue with the apical preparation to the exact working length.
- 10) Use Patterson® NiTi Files with larger taper 004 if necessary according to the anatomy of canal.
- 11) Optional finish with the final flaring step according to the obturation method.
- 12) Use Patterson® NiTi Files with larger taper 006 if necessary according to the anatomy of canal. Penetration to the exact working length is not systematically sought, except if the root canal easily receives the Patterson® NiTi Files with taper 006.
- 13) Use dedicated Paper Points to dry and dedicated gutta percha points to obturate the root canals.

8) HYGIENE, DISINFECTION, CLEANING AND STERILIZATION

- For instruments that are labelled “sterile”:
 - Patterson® NiTi File instruments are single-use devices and cannot be reused. Reuse can increase the risk of cross-contamination or breakage.
 - Disinfection, cleaning and sterilization is not applicable.
- For instruments that are labelled "nonsterile":
 - Please follow the Processing of Patterson® Products for the disinfection, cleaning and sterilization steps.
 - Do not reuse silicone stops. Remove and discard silicone stops after each use.
- Products shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.

9) ADDITIONAL INFORMATION

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

Manufactured for:

Patterson Dental Supply, Inc.
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