

ProTaper Gold[®] Rotary Files



*RX ONLY
FOR DENTAL USE ONLY*

DIRECTIONS FOR USE

SHAPING FILES (SX, S1, S2)

FINISHING FILES (F1, F2, F3, F4, F5)

1) INDICATIONS FOR USE

For the removal of dentin and shaping of the root canal.

2) CONTRAINDICATIONS

As with all mechanically driven root canal instruments, ProTaper Gold[®] files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

3) WARNINGS

Rotary files are non-sterile products and must be sterilized before use. This file contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

4) PRECAUTIONS

As with all new products, you must exercise caution until you become proficient in its use. Length determination is imperative to ensure proper instrumentation using any rotary or hand instrument. The use of radiographs and an apex locator are two acceptable methods of length determination. These instruments are to be used only in a clinical or hospital environment by qualified users following good dental practice (using gloves, glasses and a dental dam etc.). While we have implemented safeguards against possible misuse, there are several important points to remember:

- 1) A slow-speed handpiece is required for rotary file use.
- 2) Operate the hand piece at a speed of 300 RPM (Revolutions Per Minute).

ProTaper Gold [®]		
File Size	Speed [rpm]	Torque [g•cm]
ProTaper Gold [®] S1 & SX	300	520
ProTaper Gold [®] S2 & F1	300	150
ProTaper Gold [®] F2, F3, F4, F5	300	312

See motor and contra-angle requirements per motor manufacturer specifications.

- 3) Straight-line access is a prerequisite for proper root canal treatment, ProTaper Gold® files are no exception.
- 4) Always use minimal apical pressure. Never force the files down the canal.
- 5) Clean the flutes frequently during instrumentation, inspecting for signs of distortion or wear, such as uneven flutes, dull spots.
- 6) Frequently irrigate, recapitulate and irrigate the canal throughout the procedure, minimally after using each file.
- 7) Use Shaping files with a brushing action on the withdrawal stroke in order to create straight-line radicular access and to passively progress apically.
- 8) Finishing files should follow the canal passively to working length then be withdrawn. To promote the mechanical preparation objectives, take any ProTaper Gold® finishing instrument to length only one time and for no more than one second, to avoid transportation.
- 9) Exercise caution in the apical area and around significant curvatures.
- 10) When instrumenting the canal, select appropriately sized instruments as choosing an overly large file can lead to dangerous over-enlargement of the coronal portion of narrow root forms. Additionally, too large a file taken to length increases the risk of file separation.
- 11) Use the SX after S1 and S2 to optimally shape canals in shorter roots, relocate the coronal aspect of canals away from furcation concavities, or to expand the shape as desired.
- 12) ProTaper Gold® rotary files should only be used in regions of the canal that have a confirmed and reproducible glide path.

ProTaper Gold® files are manufactured with a process that results in a file that has a gold appearance. Due to this proprietary processing, ProTaper Gold® files may appear slightly curved. This is not a manufacturing defect. While the file can be easily straightened using only your fingers, it is not necessary to straighten the file prior to use. Once inside the canal, the ProTaper Gold® file will follow the anatomy.

5) ADVERSE REACTIONS

None known.

6) STEP BY STEP INSTRUCTIONS FOR ProTaper Gold® Files

ProTaper Gold® rotary files are single patient use instruments.

Recommended File Disposal: Place used files in a Biohazard Sharps container.

6.1 STERILIZATION

Files must be sterilized before use. ANSI/ADA Specification 28 recommends:

- Scrub the instruments with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.
- Place the instruments, unwrapped, in the autoclave tray.
- Use fresh distilled or deionized water.
- Steam Autoclave at 276.8°F (136°C) (plus or minus 3.6°F (2°C)) for 20 minutes.




6.2 INSTRUCTIONS FOR ProTaper Gold® FILES

The crown down technique is the technique of choice for rotary instruments.

- Create straight line access to canal orifice.
- In the presence of a viscous chelator (such as ProLube® Root Canal Conditioner) passively scout the coronal 2/3 with 10 and 15 hand files. Gently work these instruments until a smooth, reproducible glide path is confirmed. Alternatively, mechanized glide path files (such as PathFiles®) may be used after a 10 hand file.
- In the presence of NaOCl, “float” the S1 in the canal and passively “follow” the glide path. Before light resistance is encountered, laterally “brush” and cut dentin on the outstroke to improve straight-line access and apical progression. Always brush away from the furcation.
- Continue shaping with S1 as described until the depth of the 15 hand file is reached.
- Use the S2, exactly as described for the S1, until the depth of the 15 hand feel is reached.
- In the presence of a viscous chelator or NaOCl, scout the apical 1/3 with 10 and 15 hand files and gently work them until they are loose at length.
- Establish working length, confirm patency and verify the presence of a smooth reproducible glide path in the apical 1/3.
- Use the S1, with a brushing action, until working length is reached.
- Use the S2, with a brushing action, until working length is reached.
- Reconfirm working length, irrigate, recapitulate and re-irrigate, especially in more curved canals.
- Use Finishing File F1, in a “non-brushing” action, with each insertion deeper than the previous insertion until working length is reached. Do not leave the file at working length for longer than one second.
- Gauge the foramen with a 20 hand file. If the instrument is snug at length, the canal is shaped and ready to be obturated.
- If the 20 hand file is loose at length, proceed to the F2 and, when necessary the F3, F4 and F5, with the same non-brushing motion to working length, gauging after each Finishing file with 25, 30, 40 or 50 hand files respectively.
- If necessary, use the SX with a brushing motion to move the coronal aspect of the canal away from furcal concavities and/or to create more coronal shape. SX can also be used to optimally shape canals in shorter roots.
- The ProTaper sequence is always the same regardless of the length, diameter or curvature of the canal.

6.3 OBTURATION OF CANAL SYSTEMS

- Prior to obturation, the smear layer can be removed and a final rinse can be performed with Q-Mix and an activated irrigation technique such as the Endo Activator.
- Use a warm obturation method such as ProTaper® Universal obturators to encourage a dense 3D filling of the root canal system.
- A ProTaper® Universal Obturator of the same tip/taper as the last file taken to length can be used to obturate the canal. Rely on size verifiers to determine proper fit and length control of filling materials.

Symbols	EN
	Single use only
	Consult instructions for use
	Sterilize before use. Non-sterile product. Autoclave before use 273.2°F (134°C) / 20 min

Manufactured for:

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