

Prima 'Taper Gold' (Heat Treated) Ni Ti Endodontic Rotary Files

INSTRUCTIONS FOR USE (Shaping Files SX, S1, S2, Finishing Files F1, F2, F3, F4, F5)

DESCRIPTION: Prima Dental 'Taper Gold' Rotary Endodontic Files are made from an annealed nickel-titanium alloy and comprise of a tapered file, a brass handle, a coloured stopper which identifies the size of the taper, and a coloured ring identifying the Prima brand. Heat treated 'Taper Gold' files undergo a proprietary annealing process which increases the cyclic fatigue resistance and torque strength. With this proprietary processing, files may be slightly curved, this is **NOT** a manufacturing defect. Whilst the files can be easily straightened with your fingers, it is **NOT** necessary as once inside the root canal, the files will follow and conform to the natural anatomy and curvature of the root canal. Files (shapers & finishers) as shown below are available in various sizes to suit clinician preference. All files are constant tapered.

Shaping Files	File Length (mm's)	Speed (rpm)	Torque (N-cm)
SX	19	250 - 300	5.10
S1	21, 25, 31	250 - 300	5.10
S2	21, 25, 31	250 - 300	1.50
Finishing Files	File Length (mm's)		
F1	21, 25, 31	350 - 300	1.50
F2	21, 25, 31	250 - 300	3.10
F3	21, 25, 31	250 - 300	3.10
F4	21, 25, 31	250 - 300	3.10
F5	21, 25, 31	250 - 300	3.10

The speed and torque settings as indicated in the above table are for example, and may vary according to each user preference and motor capabilities.

SCOPE: These instructions are applicable to both the **sterile** and **non-sterile** Rotary Endodontic Files as offered by the Company.

Rotary Endodontic Files identified as such  do NOT require cleaning before initial use.

INDICATIONS FOR USE: Prima Dental Rotary Endodontic Files are used in endodontics for the removal of dentin and root canal shaping in a clinical or hospital environment. They are compatible with most rotary file systems, electric motors and dental hand pieces.

CONTRAINDICATIONS: Prima Dental's range of Rotary Endodontic Files contain nickel, and should therefore **NOT** be used on individuals with a known sensitivity to this metal, as in extreme cases it may cause hypersensitivity.

UNDESIRE COMPLICATIONS: Due to the nature of use and the environment in which used, the following complications may result during and from device use:

- 1/ device fracture and/or breakage,
- 2/ soft tissue damage/bleeding,
- 3/ discomfort and pain,
- 4/ infection.

WARNINGS: Please refer and comply with the warnings given below:

- 1/ rotary endodontic files delivered in a **non-sterile** condition **MUST** be cleaned and sterilised prior to initial patient use and again after every subsequent reuse,
- 2/ a rubber dam system should be used during dental procedures,
- 3/ do **NOT** use these files in a traditional rotary hand piece,
- 4/ files can be used in a clockwise rotary motor but **NOT** in a reciprocating motor, which rotates in an anti-clockwise direction,
- 5/ like all mechanically driven endodontic instruments, the files should **NOT** be used in cases with very severe and sudden apical curvatures due to heightened risk of separation,
- 6/ used files shall be considered as contaminated and as such, appropriate handling and disposal procedures must be followed when discarding used files. The use of a Biohazard Sharps container is recommended.

In the event of files being returned to Prima Dental Manufacturing Ltd, please ensure any contaminated and/or potentially contaminated files have been effectively cleaned, and are appropriately packaged for return.

PRECAUTIONS: As with all products, use these files carefully until you become proficient with device use. Always determine working length using radiographs and/or apex locator so as to properly use files. Important points to remember:

- 1/ only use with an electric motor and hand piece designed for rotary file instruments,
- 2/ straight line access is imperative for proper rotary file use and endodontic treatment,
- 3/ do **NOT** force files down the root canal, apply minimal apical pressure,
- 4/ clean the flutes frequently, inspecting for signs of distortion or wear, such as uneven flutes or dull spots,
- 5/ irrigate and lubricate the root canal frequently throughout the procedure,
- 6/ use shaping files with a brushing action on the withdrawal stroke in order to create straight line radicular access and to passively progress apically,

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7/ finishing files should follow the canal passively to working length then be withdrawn. To promote the mechanical preparation objectives, take each file to length only one time and for no more than 1 second to avoid transportation and file separation,

8/ exercise caution in the apical area and around significant curvatures,

9/ when instrumenting the canal, select appropriately sized files 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,

10/ use the SX file after the S1 and S2 files to optimally shape canals in shorter roots, relocate the coronal aspect of canals away from furcation concavities, or to expand the shape as desired,

11/ Prima 'Taper Gold' heat treated Files should only be used in regions of the canal that have a confirmed and reproducible glide path,

12/ during use, the wearing of personal protective equipment (gloves, safety glasses, masks) is recommended.

STERILISATION: Files delivered non-sterile must be cleaned and sterilised before use.

1/ scrub the instruments with a long handled bristle brush in warm water using a suitable detergent specified for the exact same purpose,

2/ rinse thoroughly with distilled, deionised or RO water,

3/ allow to dry in air,

4/ carefully place the files, either wrapped or unwrapped, in an autoclave tray,

5/ insert into a steam gravity cycle autoclave unit under pressure of 0.22NMm² at between 134 and 137°C for 20 minutes,

6/ ensure that the maximum load as stipulated by the manufacturer of the steriliser is not exceeded,

7/ the instructions given by the manufacturer of the steriliser must be followed.

Files identified as single-use  have already been sterilised and do **NOT** require further cleaning before use.

DIRECTIONS FOR USE:

RADIOGRAPHIC EVALUATION: Review different horizontally angulated radiographs to diagnostically determine the width, length and curvature of any given root and canal.

ACCESS PREPARATION: Create straight-line access to the canal orifice/s with emphasis on flaring, flattening and finishing the internal wall axis.

SHAPING TECHNIQUE:

The crown down technique is the recommended procedure for rotary instruments.

1/ files delivered in a non-sterile condition must be cleaned and sterilised before use,

2/ prepare straight-line access to canal orifice,

3/ using a lubricant suitable for root canal procedures, passively form a smooth reproducible glide path using size #10 and #15 hand files 2/3 down the length of the canal,

4/ in the presence of Sodium Hypochlorite (NaOCl), float the S1 file 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,

5/ continue shaping with the S1 file as described until the depth of the #15 hand file is reached,

6/ use the S2 file, exactly as described for the S1 file, until the depth of the #15 hand file is reached,

7/ using a suitable lubricant or Sodium Hypochlorite (NaOCl), scout the apical 1/3 with #10 and #15 hand files and gently work them until they are loose at length,

8/ establishing working length, confirm patency and verify the presence of a smooth reproducible glide path in the apical 1/3,

9/ use the S1 file, with a brushing action until working length is reached,

10/ use the S2 file, with a brushing action until working length is reached,

11/ reconfirm working length, irrigate, recapitulate and re-irrigate, especially in more curved canals,

12/ using the F1 file, in a non-brushing action and with each insertion deeper than the previous one, gently work until the working length is reached. Do **NOT** leave the file at working length for any longer than 1 second.

13/ gauge the foramen with a #20 hand file, if the instrument is snug at length, the canal is shaped and ready to be obturated,

14/ if the #20 hand file is loose at length, proceed to the F2 file and when necessary the F3, F4 and F5 files using the same non-brushing motion to working length, gauging after each finishing file with #25, 30, 40 or 50 hand files respectively,

15/ if necessary, use the SX file with a brushing motion to move the coronal aspect of the canal away from the furcal concavities and/or to create a more coronal shape. The SX file can also be used to optimally shape canals in shorter roots,

16/ the crown down technique is always the same regardless of the length, diameter or curvature of the canal.

IMPORTANT TIPS:

1/ always establish a reproducible glide path in each canal with a #15 hand file prior to rotary instrumentation,

2/ lubricate the files generously with a lubricant suitable for root canal procedures,

3/ irrigate, recapitulate and re-irrigate after using each rotary file,

4/ never force files, take to resistance only,

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5/ use all 'taper gold' files in constant rotation at speeds of between 250 and 300 RPM, the files will follow the canal,
6/ use shaping files (SX, S1 & S2) with a brushing action on the withdrawal stroke in order to create straight-line radicular access and to passively progress apically,
7/ finishing files (F1, F2, F3, F4 & F5) should follow canal passively to working length, then be withdrawn,

OBTURATION OF CANAL SYSTEMS

1/ when using a thermal carrier system, use size verifiers to determine the proper sized carrier,
2/ when using a master Gutta Percha cone that matches the largest file taken to length, remember sometimes you may need to drop down in cone tip size, if the corresponding Gutta Percha to your final rotary file does **NOT** go to length

LOT NUMBER: The Lot or batch number is a seven (7) digit number printed on the label and the packaging. **This number must be quoted in any correspondence.**

POST MARKET FEEDBACK: As part of our documented QMS and continuing commitment to monitor and act on post market feedback, Prima Dental welcome any feedback regarding the appearance and performance of our products and packaging. If you have any comments you wish to make, please contact us by writing too or e-mailing us at the address given below. Please communicate the Lot No in all correspondence.



Prima Dental Manufacturing Ltd, Stephenson Drive, Gloucester, GL2 2HA, Tel No +44 1452 729751 / Fax No +44 1452 307187
Email sales@primadental.com