

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

INSTRUCTIONS FOR USE

Prima Dental 'One Gold' Ni Ti rotary endodontic shaping files are available in small, primary, medium and large sizes dimensioned at 21, 25 and 31mm respectively

DESCRIPTION: Prima Dental 'One 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 'One 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.

File Size	Colour Coded Band	File Length (mm's)
SMALL	Yellow	21, 25, 31
PRIMARY	Red	21, 25, 31
MEDIUM	Green	21, 25, 31
LARGE	White	21, 25, 31

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 ② 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 the WaveOne® reciprocating file system and must be used in the WaveOne® motor and hand piece system using the WaveOne® motor setting.

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.

UNDESIED 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/ like all mechanically driven endodontic instruments, the files should **NOT** be used in cases with very severe and sudden curvatures.
- 5/ 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 to properly use reciprocating files. Important points to remember:

- 1/ only use with an electric motor and hand piece designed for the WaveOne® 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 and check for signs of distortion and/or wear,
- 5/ irrigate abundantly and frequently with a lubricant recommended for use in endodontics after removing any given "One Gold" shaping file from a canal,
- 6/ use a reciprocating motion with light apical pressure,
- 7/ use a gentle pecking motion with short amplitude strokes, so as to passively advance the "One Gold" shaping file along a smooth, reproducible glide path,
- 8/ remove the "One Gold" shaping file when it does **NOT** easily progress. Clean and inspect the cutting flutes, then irrigate, recapitulate with a size 010 file and re-irrigate,
- 9/ before using a "One Gold" file, scout the canal with hand files, to at least an ISO K-file size 010 with a lubricant recommended for use in endodontics,
- 10/ always initiate the shaping procedure with a PRIMARY (red) "One Gold" file in the presence of sodium hypochlorite,

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11/ during use, the wearing of personal protective equipment (gloves, safety glasses, mask) 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 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 at between 134 and 137°C with a maximum temperature of 140°C for a minimum of three (3) 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 ② have already been sterilised and do **NOT** require further cleaning before use.

INSTRUCTIONS FOR USE:

Radiographic Evaluation

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

Access Preparation

Create straight line access to the canal orifice/s with emphasis on flaring, flattening and finishing the internal axis walls.

One Gold File Technique

- 1/ prepare straight line access to canal orifice,
- 2/ in the presence of a viscous chelator, use a size 10 hand file to verify a glide path to length,
- 3/ determine working length with the help of a pre-operative radiograph and/or an apex locator, confirm patency and verify a smooth reproducible glide path up to a loose size 10 hand file,
- 4/ irrigate with a lubricant recommended for use in endodontics,
- 5/ applying gentle inward pressure, let the One Gold file passively progress through any secured region of the canal. Use the file in one or more passes until the full working length is reached,
- 6/ irrigate the expanded glide path, recapitulate and irrigate again,
- 7/ reconfirm the working length, before shaping the canal with the One Gold shaping files.

One Gold Shaping Files Technique

- 1/ establish straight line coronal access,
- 2/ in the presence of a viscous chelator, use a size 10 hand file so as to verify a glide path to length.
- 3/ expand this glide path to at least 0.15mm using either a hand file or dedicated mechanical file,
- 4/ always initiate the shaping procedure with the PRIMARY file in the presence of sodium hypochlorite,
- 5/ using gentle inward pressure let the PRIMARY file passively progress through any region of the canal that has a confirmed glide path. After shaping 2-3mm of any given canal, remove and clean the PRIMARY file, then irrigate, recapitulate with a size 10 file and re-irrigate,
- 6/ continue with the PRIMARY file in 2-3 passes, to pre-enlarge the coronal two thirds of the canal,
- 7/ utilise a brushing motion on the outstroke to eliminate coronal interferences or to enhance shaping results in canals that exhibit irregular cross-sections,
- 8/ in more restrictive canals, use a size 10 hand file in the presence of a viscous chelator, negotiate to the terminus of the canal. Gently work this file until it is completely loose at length,
- 9/ establish working length, confirm patency and verify the glide path,
- 10/ expand this glide path to at least 0.15mm using a manual or mechanical glide path,
- 11/ carry the PRIMARY file to the full working length in one or more passes. Upon reaching length, remove the file to avoid over-enlarging the foramen. Inspect the apical flutes; if they are loaded with dentinal debris, then the shape is finished*,
- 12/ if the PRIMARY file doesn't progress, then use the SMALL (yellow) file in one or more passes to working length and then use the PRIMARY file to working length to optimise the shape,
- 13/ when the shape is confirmed, proceed with disinfection protocols.

*if the PRIMARY file is loose at length with no dentinal debris in the apical flutes, continue shaping with a MEDIUM (green) file and/or LARGE (white) file until the apical flutes are loaded.

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 shown on page 3 of this IFU.

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