

wave•one[®] GOLD

reciprocating file

Directions for Use

DENTSPLY
TULSA DENTAL
SPECIALTIES

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Made in Switzerland



Single Use Only



Do Not Use If
Package Damaged



Non-autoclavable



CONSULT
INSTRUCTIONS
FOR USE

NONRETURNABLE
IF SEAL IS BROKEN

STERILE R
Standard Sealing Irradiation

Rx Only

For Dental Use Only

Directions for use WAVEONE[®] GOLD instruments

WAVEONE[®] GOLD instruments for endodontic treatment:

- SMALL WAVEONE[®] GOLD file (020 .07)
- PRIMARY WAVEONE[®] GOLD file (025 .07)
- MEDIUM WAVEONE[®] GOLD file (035 .06)
- LARGE WAVEONE[®] GOLD file (045 .05)

COMPOSITION

The cutting part of these instruments is made of nickel-titanium alloy.

1. INDICATIONS FOR USE

These instruments are to be used only in a clinical or hospital environment, by qualified users, following good dental practices (using gloves, glasses, rubber dam ...).

WAVEONE[®] GOLD instruments are for use in endodontic treatment, by shaping & cleaning the root canal system.

2. CONTRAINDICATIONS

In common with all mechanically driven root canal instruments, WAVEONE[®] GOLD instruments should not be used in cases of severe and sudden apical curvatures.

3. WARNINGS

This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

4. PRECAUTIONS

- The WAVEONE[®] GOLD files are single-use instruments.
- Clean flutes frequently and check for signs of distortion or wear.
- Irrigate abundantly and frequently after removing any given WAVEONE[®] GOLD file from a canal.
- Always initiate the shaping procedure with the PRIMARY WAVEONE[®] GOLD file in the presence of sodium hypochlorite.
- Use gentle inward pressure, with short 2-3 mm amplitude strokes, to passively advance the WAVEONE[®] GOLD file along a smooth, reproducible glide path.
- Remove WAVEONE[®] GOLD file when it does not easily progress. Clean and inspect the cutting flutes, then irrigate, recapitulate with a size O10 file and re-irrigate.
- These files are driven in precise forward/reverse reciprocating angles and must be used in reciprocating motion with dedicated DENTSPLY motors.
- WAVEONE[®] GOLD files are sold sterile and are non-autoclavable.
- WAVEONE[®] GOLD utilizes a unique approach in wire processing that increases the resistance to cyclic fatigue compared to standard NiTi. Due to this processing, WAVEONE[®] GOLD files may appear slightly curved. This is not a manufacturing defect. It is not necessary to straighten the file prior to use. Once inside the canal, the WAVEONE[®] GOLD file will follow the glide path, conforming to natural curvatures.

5. ADVERSE REACTIONS

As with all mechanically-driven root canal instruments, WAVEONE[®] GOLD files should not be used in cases of severe and sudden apical curvature due to high risk of breakage.

6. STEP-BY-STEP INSTRUCTIONS FOR WAVEONE® GOLD FILES

6.1 Radiographic Evaluation

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

6.2 Access Preparation

Create straight-line access to the canal orifice(s) with emphasis on flaring, flattening, and finishing the internal axial walls.

6.3 Precautions

- Irrigate abundantly and frequently after removing any given WAVEONE® GOLD file from the canal.
- Use a gentle inward pressure, with short 2-3 mm amplitude strokes, to passively advance the WAVEONE® GOLD file along a smooth, reproducible glide path.
- Remove a WAVEONE® GOLD file when it does not easily progress. Clean and inspect the cutting flutes, then irrigate, recapitulate with a size O10 file and re-irrigate.

6.4 WAVEONE® GOLD SHAPING TECHNIQUE

- 1) Establish straight-line coronal and radicular access.
- 2) In the presence of a viscous chelator, use a size O10 hand file to verify a glide path to length. In more restrictive canals, use a size O10 hand file in any region of a canal to create a glide path.
- 3) Expand this glide path to at least 0.15 mm using either a manual or dedicated mechanical file, such as PROGLIDER® rotary glide path file or PATHFILE® root canal drills.
- 4) ALWAYS initiate the shaping procedure with the PRIMARY file (O25/O7 red) in the presence of sodium hypochlorite.
- 5) Use gentle inward pressure and let the PRIMARY file passively progress through any region of the canal that has a confirmed glide path. After shaping 2-3 mm of any given canal, remove and clean the PRIMARY file, then irrigate, recapitulate with a size O10 hand 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) Utilize 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 O10 hand file, in the presence of 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 0.15 mm using a manual or mechanical glide path file.
- 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 doesn't progress then use the SMALL file (O20/O7 yellow) in one or more passes to working length and then use the PRIMARY file to working length to optimize the shape.
- 13) When the shape is confirmed, proceed with 3-D disinfection protocols.

*If the PRIMARY file is loose at length with no dentinal debris in the apical flutes, continue shaping with MEDIUM file (O35/O6 green) and/or LARGE file (O45/O5 white) until the apical flutes are loaded.

7. DISINFECTION, CLEANING AND STERILIZATION

WAVEONE® GOLD is intended for single-use only.

Disinfection, cleaning and sterilization procedures are not recommended.

Re-use of WAVEONE® GOLD can increase the risk of cross contamination and breakage.