

WaveOne[®] Gold System



*RX ONLY
FOR DENTAL USE ONLY*

DIRECTIONS FOR USE

ENDODONTIC STERILE RECIPROCATING GLIDE PATH FILE REF. B ST W1GG &
ENDODONTIC STERILE RECIPROCATING SHAPING FILES REF A 0751, A 0753, A 0756, A 0757

WaveOne[®] Gold Glider file:

- WaveOne[®] Gold Glider file No 015 .02

WaveOne[®] Gold shaping files:

- SMALL WaveOne[®] Gold file No 020 .07
- PRIMARY WaveOne[®] Gold file No 025 .07
- MEDIUM WaveOne[®] Gold file No 035 .06
- LARGE WaveOne[®] Gold file No 045 .05

COMPOSITION

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

1) INDICATIONS FOR USE

WaveOne[®] Gold Glider files are recommended to be used in endodontic treatment to expand the secured glide path in preparation for the reciprocating mechanized WaveOne[®] Gold files system.

WaveOne[®] Gold shaping files are intended for use in endodontic treatment, by shaping & cleaning the root canal system.

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 ...).

2) CONTRAINDICATIONS

None known.

3) WARNINGS

- These products contains nickel and should not be used for individuals with known allergic sensitivity to this metal.
- It is highly recommended to use a rubber dam system during the endodontic procedure.
- WaveOne[®] Gold Glider files & WaveOne[®] Gold shaping files are provided sterile and cannot be reused. Re-use would increase the risk of cross contamination or breakage.

4) PRECAUTIONS

WaveOne® Gold Glider files & WaveOne® Gold shaping files:

- WaveOne® Gold Glider files & WaveOne® Gold shaping files are single use instruments; re-use is not allowed. They can become less efficient after multiple use causing undue stress to the files. This can lead to files separation.
- WaveOne® Gold Glider files & WaveOne® Gold shaping files are sold sterile and are non-autoclavable.
- WaveOne® Gold Glider files & WaveOne® Gold shaping files should not be used in cases of severe and sudden apical curvatures when mechanically driven.
- Clean flutes frequently and check for signs of distortion or wear.
- Irrigate abundantly and frequently after removing any given WaveOne® Gold Glider file & WaveOne® Gold shaping file from a canal.
- Exercise caution in canals that divide, and/or exhibit abrupt curvatures or recurvatures.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- WaveOne® Gold Glider files & WaveOne® Gold shaping files should not be fully immersed in a sodium hypochlorite solution (NaOCl).
- Irrigate the root canal copiously and frequently during the procedure.
- Use a reciprocating motion with light apical pressure.
- Use a gentle inward pecking motion, with short amplitude strokes, to passively advance the WaveOne® Gold Glider file or the WaveOne® Gold shaping file along a smooth, reproducible glide path.
- Remove a WaveOne® Gold Glider file or a WaveOne® 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.
- WaveOne® Gold Glider files & WaveOne® Gold shaping files are recommended to be used mechanically (manually in severe curvatures) with a motor having the approved WaveOne® / WaveOne® Gold settings.
- WaveOne® Gold Glider files & WaveOne® Gold shaping files use a unique approach in wire processing that increases the resistance to cyclic fatigue compared to standard NiTi. Due to this processing, WaveOne® Gold Glider files & WaveOne® Gold shaping 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 Glider files & the WaveOne® Gold shaping files will follow the glide path, conforming to natural curvatures.

WaveOne® Gold Glider files:

- Before using a WaveOne® Gold Glider file, scout the canal with hand files, to at least an ISO K-file size 010 with a lubricant such as ProLube® Root Canal Conditioner.

WaveOne® Gold shaping files:

- Always initiate the shaping procedure with the PRIMARY WaveOne® Gold file in the presence of sodium hypochlorite.

5) ADVERSE REACTIONS

None known.

6) STEP-BY-STEP INSTRUCTIONS FOR THE WaveOne® Gold System

6.1 Radiographic evaluation

Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root 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 Glider file & WaveOne® Gold shaping file from a canal.
- Remove a WaveOne® Gold Glider file & WaveOne® Gold shaping files when it does not easily progress. Clean and inspect the cutting flutes, then irrigate, recapitulate with a size 010 K-file and re-irrigate.
- Use a gentle inward pecking motion, with short amplitude strokes, to passively advance the WaveOne® Gold Glider file or the WaveOne® Gold shaping file along a smooth, reproducible glide path.

6.4 WaveOne® Gold Glider files technique

- 1) Prepare straight line access to canal orifice.
- 2) In the presence of a viscous chelator, explore the canal up to a size 010 hand file.
- 3) Determine working length with the help of a preoperative radiograph [mandatory] and/or an apex locator, confirm patency and verify a smooth reproducible glide path up to a loose size 010 hand file.
- 4) Irrigate.
- 5) With gentle inward pressure, let the WaveOne® Gold Glider file passively progress through any secured region of the canal. Use the WaveOne® Gold Glider 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 WaveOne® Gold shaping system.

6.5 WaveOne® Gold shaping files technique

- 1) Establish straight-line coronal and radicular access.
- 2) In the presence of a viscous chelator, use a size 010 hand file to verify a glide path to length. In more restrictive canals, use a size 010 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 PathFile, ProGlider or the dedicated WaveOne® Gold Glider file.
- 4) ALWAYS initiate the shaping procedure with the PRIMARY file (025/07 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 010 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 010 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 (020/07 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 (035/06 green) and/or LARGE file (045/05 white) until the apical flutes are loaded.

7) DISINFECTION, CLEANING AND STERILIZATION

The WaveOne® Gold Glider files & WaveOne® Gold shaping files are intended for single use only. Disinfection, cleaning and sterilization procedures are not recommended.

Re-use of WaveOne® Gold Glider files & WaveOne® Gold shaping files can increase the risk of cross contamination and breakage.

| Symbols | EN |
|---|---------------------------------|
|  | For single use only |
|  | Consult instructions for use |
|  | Nonreturnable if seal is broken |
|  | Do not use if package damaged |
|  | Sterilized by radiation |
|  | Not-autoclavable |

Manufactured for:

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