

WaveOne[®] Gold System

US

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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