

M3 W-One Gold FILES

FOR DENTAL USE ONLY

DIRECTIONS FOR USE

M3 W-One Gold shaping files:

- M3 W-One Gold SMALL file #20/07vt
- M3 W-One Gold PRIMARY file #25/07vt
- M3 W-One Gold MEDIUM file #35/06vt
- M3 W-One Gold LARGE file #45/05vt

COMPOSITION

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

1) INDICATIONS FOR USE

M3 W-One Gold Glider files are recommended to be used in endodontic treatment to expand the secured glide path in preparation for the reciprocating mechanized M3 W-One Gold files system.

M3 W-One 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.
- M3 W-One Gold shaping files are provided sterile and cannot be reused. Re-use would increase the risk of cross contamination or breakage.

4) PRECAUTIONS

M3 W-One Gold shaping files:

- M3 W-One 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.
- M3 W-One Gold shaping files are sold sterile and are non-autoclavable.

- M3 W-One 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 M3 W-One 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).
- M3 W-One 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 M3 W-One Gold shaping file along a smooth, reproducible glide path.
- Remove a M3 W-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.
- M3 W-One Gold shaping files are recommended to be used mechanically (manually in severe curvatures) with a motor having the approved M3 W-One Gold settings.
- M3 W-One 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, M3 W-One 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 M3 W-One Gold shaping files will follow the glide path, conforming to natural curvatures.

5) ADVERSE REACTIONS

None known.

6) STEP-BY-STEP INSTRUCTIONS FOR THE M3 W-One 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 M3 W-One Gold shaping file from a canal.
- Remove a M3 W-One 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 M3 W-One Gold shaping file along a smooth, reproducible glide path.

6.4 M3 W-One 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.
- 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.

7) DISINFECTION, CLEANING AND STERILIZATION

M3 W-One Gold shaping files are intended for single use only. Disinfection, cleaning and sterilization procedures are not recommended.

Re-use of M3 W-One Gold shaping files can increase the risk of cross contamination and breakage.

Manufacturer

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