



1. Product Name

NIC® W+ Gold Heat-Treated NiTi Reciprocating Files

This IFU applies to the NIC® W+ Tunnel glide path file and NIC® W+ shaping files listed below.

2. Product Description

NIC® W+ files are engine-driven nickel-titanium root-canal instruments intended for reciprocating root canal preparation.

The files are manufactured from MaxTech 3.0 gold heat-treated NiTi alloy, designed to provide a balance of cutting efficiency, flexibility, and cyclic fatigue resistance for conventional endodontic treatment.

MaxTech 3.0 is a specialized heat-treatment process that gives the alloy its gold appearance and improves flexibility compared with standard NiTi, while maintaining efficient cutting performance.

The NIC® W+ system includes a W+ Tunnel File 15/.02, used to build and expand a smooth glide path before shaping, and W+ shaping files used for canal shaping and cleaning.

- Reciprocating movement
- Single-file shaping technique
- Strong cutting efficiency
- Progressive taper design and variable cutting flute length
- Parallelogram cross-section for W+ shaping files

3. Composition

The cutting part of the instruments is made of MaxTech 3.0 gold heat-treated nickel-titanium alloy.

Component	Material
Working part	MaxTech 3.0 heat-treated NiTi alloy
Shank	Metal alloy
Stopper	Silicone rubber

4. Available Files

File	Colour	ISO Size	Taper	Available Lengths
W+ Tunnel	White	015	.02	21 mm, 25 mm, 31 mm
W+ Small	Yellow	020	.07	21 mm, 25 mm, 31 mm
W+ Primary	Red	025	.07	21 mm, 25 mm, 31 mm
W+ Medium	Green	035	.06	21 mm, 25 mm, 31 mm
W+ Large	White	045	.05	21 mm, 25 mm, 31 mm



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5. Intended Use

NIC® W+ reciprocating files are dental root-canal instruments intended for use by qualified dental professionals for cleaning, shaping, and preparing root canals during endodontic treatment.

The files are intended to be used with a compatible endodontic motor in reciprocating mode.

6. Indications for Use

The NIC® W+ Tunnel File 15/.02 is intended to expand a secured glide path before using NIC® W+ shaping files.

The NIC® W+ shaping files are intended for root canal shaping and cleaning in permanent teeth, including conventional, narrow, and curved canals, provided a smooth and reproducible glide path has been established.

These instruments are intended for use only in a clinical or hospital environment by qualified dental professionals following standard dental safety protocols, including gloves, protective eyewear, mask, and rubber dam isolation.

7. Contraindications

- Do not use this product in patients with known allergic sensitivity to nickel-titanium alloy or any component of the device.
- Do not use mechanically in canals with severe, sudden apical curvatures, complex canal divisions, or anatomy where safe passive file progression cannot be achieved.

8. Warnings

- For dental professional use only.
- The product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.
- Always use rubber dam isolation during endodontic treatment.
- These files are supplied non-sterile and must be sterilized before first use.
- Single-use only. Do not reuse.
- Reuse may increase the risk of cross-contamination, loss of cutting efficiency, or file separation.
- Use only in reciprocating motion. Do not use in continuous rotary motion.
- Do not use the file if the package is damaged.
- Do not use the file if it is deformed, unwound, corroded, fractured, or shows signs of wear.
- Do not force the file apically. Excessive apical pressure may cause file separation, ledging, transportation, perforation, or other procedural complications.

9. Precautions

- Wear appropriate personal protective equipment, including gloves, mask, and protective eyewear.
- Review pre-operative radiographs to determine canal width, length, and curvature.
- Establish straight-line access before using the file.
- Confirm a smooth, reproducible glide path before shaping.



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- Irrigate copiously and frequently during the procedure.
- Clean flutes frequently and inspect for distortion or wear.
- Do not fully immerse the files in sodium hypochlorite solution.
- Use a reciprocating motion with light apical pressure.
- Use a gentle inward pecking motion with short amplitude strokes.
- If a file does not progress easily, remove it, clean and inspect the flutes, irrigate, recapitulate with a size 010 K-file, and re-irrigate.
- Exercise caution in canals that divide or exhibit abrupt curvatures or recurvatures.
- Due to heat treatment, the file may appear slightly curved. This is not necessarily a manufacturing defect. It is not necessary to straighten the file before use. Once inside the canal, the file will follow the prepared glide path and natural canal curvature.

10. Recommended Motor Settings

Use a reciprocating endodontic motor with a WaveOne Gold®-compatible reciprocating program, or manually enter the following settings where custom settings are required.

File Type	Motion	Speed	Torque
NIC® W+ Tunnel File	Reciprocating	-	-
NIC® W+ Shaping Files	Reciprocating	-	-

Where angle settings are required:

File Type	Cutting Angle	Release Angle	Speed	Torque
All NIC® W+ files	150° CCW	30° CW	-	-

Alternative motor display format:

File Type	Forward	Reverse	Speed	Torque
All NIC® W+ files	150°	30°	-	-

Note: Motor terminology may vary by manufacturer. Confirm the correct reciprocating direction and program before clinical use.

11. Adverse Reactions

None known when the product is used as directed.

Possible procedural complications associated with improper use of endodontic instruments may include file separation, canal transportation, ledging, perforation, blockage, or extrusion of debris.

12. Step-by-Step Clinical Instructions

12.1 Radiographic Evaluation

Review pre-operative radiographs from different horizontal angulations to determine the width, length, and curvature of each root canal.



12.2 Access Preparation

1. Create straight-line coronal and radicular access to the canal orifice.
2. Emphasize flaring, flattening, and finishing of the internal axial walls.
3. Irrigate the pulp chamber and canal system.

12.3 Glide Path Preparation with W+ Tunnel File

1. In the presence of a viscous chelator or lubricant, explore the canal with a size 010 stainless steel hand file.
2. Determine working length using a pre-operative radiograph and/or apex locator.
3. Confirm patency and verify a smooth, reproducible glide path to a loose size 010 hand file.
4. Irrigate the canal.
5. Use the NIC® W+ Tunnel File 15/.02 with gentle inward pressure.
6. Allow the W+ Tunnel File to passively progress through the secured region of the canal.
7. Use the W+ Tunnel File in one or more passes until the full working length is reached.
8. Irrigate the expanded glide path.
9. Recapitulate with a size 010 K-file.
10. Irrigate again.
11. Reconfirm working length before using the W+ shaping files.

12.4 Shaping Technique with W+ Files

1. Establish straight-line coronal and radicular access.
2. Use a size 010 hand file with lubricant or chelator to verify a glide path to length.
3. In restrictive canals, use a size 010 hand file to create a reproducible glide path.
4. Expand the glide path manually or mechanically before shaping. The NIC® W+ Tunnel File 15/.02 may be used for this step.
5. Always initiate the shaping procedure with the NIC® W+ Primary File 25/.07 red in the presence of sodium hypochlorite.
6. Use gentle inward pressure and allow the Primary file to passively progress through any region of the canal with a confirmed glide path.
7. After shaping approximately 2-3 mm of the canal, remove and clean the Primary file.
8. Irrigate, recapitulate with a size 010 hand file, and re-irrigate.
9. Continue with the Primary file in 2-3 controlled passes to pre-enlarge the coronal two-thirds of the canal.
10. Use a brushing motion on the outstroke to eliminate coronal interferences or improve shaping in canals with irregular cross-sections.
11. In more restrictive canals, use a size 010 hand file with viscous chelator to negotiate to the canal terminus.
12. Work the size 010 hand file gently until it is loose at working length.
13. Reconfirm working length, patency, and glide path.
14. Carry the Primary file to full working length in one or more passes.
15. Once working length is reached, remove the file immediately to avoid over-enlargement.
16. Inspect the apical flutes. If the apical flutes are loaded with dentinal debris, shaping is complete.
17. If the Primary file does not progress, use the NIC® W+ Small File 20/.07 yellow in one or more passes to working length, then return to the Primary file to optimize the shape.
18. If the Primary file is loose at working length and there is no dentinal debris in the apical flutes, continue shaping with the NIC® W+ Medium File 35/.06 green and/or NIC® W+ Large File 45/.05 white until the desired apical shape is achieved.
19. When the shape is confirmed, proceed with the clinician's preferred irrigation, disinfection, drying, and obturation protocol.



13. Cleaning, Disinfection, and Sterilization

NIC® W+ files in this version are supplied non-sterile and must be sterilized before first clinical use.

Recommended pre-use sterilization cycle:

Method	Temperature	Holding Time
Steam autoclave	134°C	18 minutes

- Use only a validated steam sterilization process.
- Allow instruments to dry completely before clinical use.
- After clinical use, discard the file in an appropriate biohazard sharps container.
- Do not clean, disinfect, sterilize, or reuse the file after clinical use.

14. Storage Conditions

- Store in the original packaging.
- Store at room temperature.
- Keep dry, clean, and away from direct sunlight.
- Avoid high temperature and high humidity.
- Avoid damage to packaging materials during transportation and storage.
- Do not use after the expiry date.

15. Shelf Life

The product shelf life is 5 years from the date of manufacture, unless otherwise stated on the product label.

16. Product Specifications

Feature	Specification
Material	MaxTech 3.0 gold heat-treated NiTi alloy
Motion	Reciprocating
Glide path file	W+ Tunnel 15/.02, white, 21 mm / 25 mm / 31 mm
Shaping files	20/.07, 25/.07, 35/.06, 45/.05
Shaping file cross-section	Parallelogram
Technique	Reciprocating glide path and shaping technique
Use	Single-use
Sterility	Non-sterile; sterilize before first use
Available lengths	21 mm, 25 mm, 31 mm



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Instruction For Use

17. Symbols

Symbol	Standard
	Manufacturer/ Legal Manufacturer (ISO 15223-1)
	Reference Number (ISO 15223-1)
	Batch Code (ISO 15223-1)
	Used-by Date (ISO 15223-1)
	Consult instructions for use (ISO 15223-1)
	Caution (ISO 15223-1)
	Made using heat-treated Nickel-Titanium alloy
	European conformity:MDD 93/42/EEC IVDD 98/79/EC Article 16.2
	Date of manufacture: ISO 15223-1:2016
	Authorized representative in Europe: ISO 15223-1:2016
	Medical device: ISO 15223-1:2021
	Reciproc: Indicates reciprocating movement
	Medical device that has not been subjected to a sterilization process. 5.2.7
	Autoclavable at the indicated temperature



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