



NIC® MH Heat-Treated CM Wire Rotary Files

Instruction For Use (Non-Sterile)

1. Product Name

NIC® MH Heat-Treated CM Wire Rotary Files

This IFU applies to the NIC® MH rotary files listed below.

2. Product Description

NIC® MH files are engine-driven nickel-titanium root-canal instruments intended for continuous rotary root canal preparation.

The files are manufactured from NIC® MaxTech 9.0 heat-treated CM Wire, designed to provide high flexibility, reduced shape memory, and the ability to follow canal curvature without actively straightening the anatomy.

The MH system provides a flexible constant-taper rotary workflow with .04 and .06 tapers, covering ISO tip sizes 17 through 45 for progressive shaping and straightforward obturation planning.

The file design includes a triangular cross-section, a non-cutting guiding tip, a 1 0.8-1.0 mm maximum flute diameter, and an 11 mm handle for improved posterior access.

- Continuous clockwise rotary movement
- Flexible constant-taper shaping workflow
- .04 and .06 constant tapers
- ISO tip sizes 17 through 45
- MaxTech 9.0 heat-treated CM Wire
- Reduced shape memory
- Triangular cross-section
- Non-cutting guiding tip
- 0.8-1.0 mm maximum flute diameter
- 11 mm handle
- 6 instruments per pack

3. Composition

The cutting part of the instruments is made of MaxTech 9.0 heat-treated CM Wire nickel-titanium alloy.

Component	Material
Working part	MaxTech 9.0 heat-treated CM Wire NiTi alloy
Shank	Metal alloy
Stopper	Silicone rubber

4. Available Files

The MH range includes 14 size-and-taper combinations. Files larger than 45/.04 or 45/.06 are not included in this system.

Taper	Available ISO Sizes	Motion	Available Lengths
.04	17, 20, 25, 30, 35, 40, 45	Continuous clockwise rotation	See product label
.06	17, 20, 25, 30, 35, 40, 45	Continuous clockwise rotation	See product label

5. Intended Use

NIC® MH rotary 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 torque-controlled endodontic motor in continuous clockwise rotation. They are not intended for reciprocating motion.

6. Indications for Use

NIC® MH files are indicated for the removal of dentin and shaping of the root canal system in permanent teeth.

MH files are intended for flexible constant-taper shaping in routine and curved canals where the clinician requires ISO 17-45 sizes and a choice between .04 and .06 tapers.

The .04 taper may be selected when conservative enlargement and flexibility are priorities. The .06 taper may be selected selectively when greater taper or coronal enlargement is clinically appropriate.

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, calcified anatomy, or anatomy where safe passive file progression cannot be achieved.

8. Warnings

- For dental professional use only.
- The product contains nickel-titanium and should not be used for individuals with known allergic sensitivity to this material.
- Always use rubber dam isolation during endodontic treatment.
- These files are supplied non-sterile and must be sterilized before first use.
- Do not use the file if the package is damaged.
- Single-use only. Do not reuse.
- Reuse may increase the risk of cross-contamination, loss of cutting efficiency, or file separation.
- Use only with a compatible torque-controlled endodontic motor operating in continuous clockwise rotation. Do not use in reciprocating motion.
- 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, blockage, or other procedural complications.
- Follow the speed and torque settings stated in the current NIC MH IFU, product label, or approved motor preset. Do not automatically apply settings published for another manufacturer's file system.

9. Precautions

- Wear appropriate personal protective equipment, including gloves, mask, and protective eyewear.
- Review pre-operative radiographs to determine canal width, length, and curvature.
- Determine working length using radiographs and/or an apex locator.
- Establish straight-line access before using the file.
- Do not introduce an MH rotary file into an unscouted canal.
- Scout the canal with stainless steel K-files and establish a smooth, reproducible glide path before rotary shaping.
- Confirm patency with a size 010 K-file and establish a glide path with at least a size 015 K-file to working length.
- Use minimal apical pressure and allow the file to advance passively.
- Use gentle pecking movements and controlled short strokes during rotary preparation.
- Clean the flutes frequently and inspect for distortion, unwinding, wear, corrosion, or dull cutting edges.
- Frequently irrigate, recapitulate, and re-irrigate during instrumentation, minimally after each file.
- If resistance is encountered before working length, withdraw the file, irrigate, recapitulate, and use a smaller file rather than forcing advancement.
- Use 17/.04 to establish the rotary pathway, then use 25/.04 as the primary shaping file when clinically appropriate.



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- Increase sequentially to 30, 35, 40 or 45 only when a larger apical preparation is clinically indicated.
- Use .04 taper files when flexibility and conservative enlargement are priorities.
- Use .06 taper files selectively when additional taper or coronal enlargement is appropriate.
- Do not use .06 taper automatically in severe curvature.
- Due to MaxTech 9.0 CM Wire heat treatment, the file may show a slight natural curve. Do not straighten the file before use unless current NIC instructions specifically require it.
- Replace the file whenever stress, deformation, unwinding, or cutting deterioration is suspected.

10. Recommended Motor Settings

Use a compatible electric, torque-controlled endodontic motor and handpiece in continuous clockwise rotation.

MH-specific speed and torque values must follow the current NIC MH instructions for use, product label, or an NIC-approved motor preset. Do not automatically copy speed or torque settings from another manufacturer's file system.

File Type	Motion	Speed	Torque
NIC® MH .04 taper files	Continuous clockwise rotation	Refer to current NIC IFU / product label	Refer to current NIC IFU / product label
NIC® MH .06 taper files	Continuous clockwise rotation	Refer to current NIC IFU / product label	Refer to current NIC IFU / product label

Note: Motor terminology may vary by manufacturer. Confirm motion, speed, torque, and handpiece requirements 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, soft tissue injury, pain, infection, 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, visibility, and curvature of each root canal.

12.2 Access Preparation

1. Create straight-line coronal and radicular access to the canal orifice.
2. Remove restrictive coronal interference while preserving sound dentin.
3. Irrigate the pulp chamber and canal system.

12.3 Glide Path Preparation

1. Explore the canal with stainless steel hand files and an appropriate root-canal lubricant.
2. Confirm working length with at least a size 010 K-file.
3. Enlarge the glide path until a smooth and reproducible size 015 K-file reaches working length.
4. Pre-curve hand files for curved or difficult anatomy when required.
5. Irrigate and recapitulate frequently during glide-path preparation.
6. Do not begin rotary shaping until the glide path is secure.

12.4 Initial Shaping - 17/.04

1. Introduce the 17/.04 MH file into the established glide path.



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2. Advance passively in one or more controlled passes until working length is reached.
3. Use gentle pecking movements and minimal apical pressure.
4. Withdraw and clean the flutes frequently.
5. Irrigate and recapitulate with a small hand file between passes when needed.

12.5 Primary Shaping - 25/.04

1. Passively advance the 25/.04 file toward working length.
2. If the 25/.04 file does not reach working length without resistance, withdraw, irrigate, recapitulate, and use 20/.04 to establish the pathway.
3. After the smaller file reaches working length, return to 25/.04 to complete the primary preparation when clinically appropriate.
4. Clean the flutes and replenish irrigant before each re-entry.
5. Do not increase apical pressure to force 25/.04 to working length.

12.6 Sequential Enlargement When Needed

1. When 25/.04 reaches working length with minimal resistance, or when a larger apical preparation is clinically indicated, enlarge sequentially with 30, 35, 40 and 45.
2. Select .04 or .06 taper according to canal anatomy and the desired final shape.
3. Increase tip size sequentially; do not skip sizes.
4. Use .04 taper when flexibility and conservative shaping are priorities.
5. Use .06 taper selectively for greater coronal enlargement in suitable anatomy.
6. Irrigate and recapitulate between every rotary file.
7. Stop and reassess when the file no longer advances passively.

12.7 Verification and Obturation

1. Verify the final preparation and working length with the corresponding hand file.
2. Confirm that the selected master cone fits the prepared canal with appropriate apical control.
3. Complete the final irrigation and drying protocol.
4. Obturate using dimensionally compatible paper points, gutta-percha points, sealer, and the clinician's preferred obturation technique.
5. Confirm tug-back and radiographic fit before final sealer placement.
6. Follow the instructions for use for the selected sealer and obturation system.

13. Cleaning, Disinfection, and Sterilization

NIC[®] MH 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.



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- 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 6.0 heat-treated CM Wire NiTi alloy
Motion	Continuous clockwise rotation
Available files	17/.04, 20/.04, 25/.04, 30/.04, 35/.04, 40/.04, 45/.04; 17/.06, 20/.06, 25/.06, 30/.06, 35/.06, 40/.06, 45/.06
Taper options	.04 and .06 constant tapers
Size range	ISO 17 through 45
Cross-section	Triangular
Tip design	Non-cutting guiding tip
Maximum flute diameter	1.0 mm
Handle length	11 mm
Technique	Flexible constant-taper rotary shaping
Packaging	6 instruments per pack
Use	Single-use
Sterility	Non-sterile; sterilize before first use
Available lengths	See product label

16.1 File Specifications

File	Tip	Taper	Cross Section	MFD	Motion
17/.04	0.17 mm	4%	Triangular	0.8 mm	Continuous rotation
20/.04	0.20 mm	4%	Triangular	0.8 mm	Continuous rotation
25/.04	0.25 mm	4%	Triangular	0.8 mm	Continuous rotation
30/.04	0.30 mm	4%	Triangular	0.8 mm	Continuous rotation
35/.04	0.35 mm	4%	Triangular	0.8 mm	Continuous rotation
40/.04	0.40 mm	4%	Triangular	1.0 mm	Continuous rotation
45/.04	0.45 mm	4%	Triangular	1.0 mm	Continuous rotation
17/.06	0.17 mm	6%	Triangular	1.0 mm	Continuous rotation
20/.06	0.20 mm	6%	Triangular	1.0 mm	Continuous rotation
25/.06	0.25 mm	6%	Triangular	1.0 mm	Continuous rotation
30/.06	0.30 mm	6%	Triangular	1.0 mm	Continuous rotation
35/.06	0.35 mm	6%	Triangular	1.0 mm	Continuous rotation
40/.06	0.40 mm	6%	Triangular	1.0 mm	Continuous rotation
45/.06	0.40 mm	6%	Triangular	1.0 mm	Continuous rotation

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
	Adjustment of rotation speed ISO 21531 (ISO no. 7000-0258)
	Medical device that has not been subjected to a sterilization process. 5.2.7
	Autoclavable at the indicated temperature



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