



NIC® V Blue Heat-Treated NiTi Reciprocating Files

Instruction For Use (Non-Sterile)

1. Product Name

NIC® V Blue Heat-Treated NiTi Reciprocating Files

This IFU applies to the NIC® V Blue reciprocating shaping files listed below.

2. Product Description

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

The files are manufactured from MaxTech 6.0 blue heat-treated NiTi alloy, designed to provide high flexibility, reduced rigidity, and improved cyclic fatigue resistance for curved and complex root-canal anatomy.

NIC® V Blue files provide a simplified three-size reciprocating workflow. In many routine cases, one selected file can complete canal preparation, with R25 serving as the primary size for most clinical situations.

The file design includes an S-shaped cross-section for cutting efficiency and debris removal, and a regressive taper designed to limit unnecessary coronal dentin removal while maintaining apical shaping.

- Reciprocating movement
- Three-file size range: R25, R40 and R50
- MaxTech 6.0 blue heat-treated NiTi alloy
- Can be gently pre-bent for improved access
- S-shaped cross-section
- Regressive taper design
- 6 instruments per pack

3. Composition

The cutting part of the instruments is made of MaxTech 6.0 blue heat-treated nickel-titanium alloy.

Component	Material
Working part	MaxTech 6.0 heat-treated NiTi alloy
Shank	Metal alloy
Stopper	Silicone rubber

4. Available Files

File	ISO Size	Taper	Motion	Available Lengths
R25	025	8% variable, regressive	Reciprocating	21 mm, 25 mm, 31 mm
R40	040	6% variable, regressive	Reciprocating	21 mm, 25 mm, 31 mm
R50	050	5% variable, regressive	Reciprocating	21 mm, 25 mm, 31 mm

5. Intended Use

NIC® V Blue 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 the authorized reciprocating mode. They are not intended for continuous rotary motion.



6. Indications for Use

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

The V Blue system includes three shaping sizes: R25, R40 and R50. R25 is the usual primary size for most routine canals. R40 or R50 should be selected only when canal anatomy and apical gauging indicate that a larger final preparation is appropriate.

When permitted by the current NIC product labelling, V Blue may also be used to assist with removal of gutta-percha or other compatible obturation material during retreatment.

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 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 with a compatible endodontic motor operating in the authorized reciprocating mode. Never use continuous rotation.
- 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, blockage, 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.
- Determine working length using radiographs and/or an apex locator.
- Establish straight-line access before using the file.
- Scout the canal with a small hand file and confirm a reproducible pathway before shaping.
- Create a glide path to at least ISO 015 whenever resistance, curvature, or limited patency indicates that additional preparation is needed.
- Use only very light apical pressure and allow the instrument to advance passively.
- Use slow, controlled in-and-out pecking movements with an amplitude of approximately 3 mm or less.
- Withdraw after about three pecks, clean the flutes, irrigate, and recapitulate before continuing.
- If the file does not progress easily, remove it, clean and inspect the flutes, irrigate, recapitulate with a size 010 or 015 hand file, and re-irrigate.
- Do not fully immerse the files in sodium hypochlorite solution.
- Exercise caution in canals that divide or exhibit abrupt curvatures, recurvatures, calcification, ledges, or other complex anatomy.
- Select the final size according to canal anatomy, apical gauging, and clinical judgment. Do not automatically enlarge every canal beyond R25.
- Due to MaxTech 6.0 heat treatment, the file may be gently pre-bent to improve access. Once inside the canal, the file should follow the prepared glide path and natural canal curvature.
- Replace the file whenever stress, deformation, unwinding, or cutting deterioration is suspected.



10. Recommended Motor Settings

Use a compatible endodontic motor with the manufacturer-authorized reciprocating program specified in the current NIC instructions for use. Reciprocation angles and preset names may differ between motors, so a continuous-rotation speed or torque setting must not be substituted.

File Type	Motion	Speed	Torque
R25	Compatible reciprocating mode	-	-
R40	Compatible reciprocating mode	-	-
R50	Compatible reciprocating mode	-	-

Note: Motor terminology may vary by manufacturer. Confirm the correct reciprocating program before clinical use. Never operate V Blue files in continuous clockwise rotation.

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, 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. Emphasize flaring, flattening, and finishing of the internal axial walls.
3. Irrigate the pulp chamber and canal system.

12.3 File Selection and Glide Path

1. Assess canal visibility, estimated width, length, and curvature.
2. For a narrow or poorly visible canal, begin with R25.
3. When the canal is clearly visible, passive hand-file gauging may help determine whether R40 or R50 is appropriate.
4. Scout the canal with a small stainless steel hand file using lubricant or irrigant.
5. Confirm patency and a reproducible pathway with a size 010 hand file, and at least a size 015 hand file when anatomy requires additional glide-path preparation.
6. Create or expand the glide path manually or mechanically when resistance, curvature, or limited patency indicates that additional preparation is needed.
7. Reconfirm working length before using the reciprocating file.

12.4 Reciprocating Shaping

1. Place irrigant in the access cavity and introduce the selected V Blue file into the canal entrance.
2. Activate the authorized reciprocating mode and advance the instrument with slow in-and-out pecking movements not exceeding approximately 3 mm.
3. Use very light apical pressure and allow the instrument to advance passively.
4. After about three pecks, withdraw the file, clean the flutes, irrigate, and recapitulate before continuing.



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5. A gentle brushing action may be used on withdrawal to enlarge the canal entrance when clinically appropriate.
6. Continue progressively until the file reaches working length, cleaning and irrigating after each short series of pecks.
7. If the file does not progress, stop, withdraw, clean, irrigate, recapitulate with a small hand file, and reassess the glide path.

12.5 Apical Gauging and Final Size Verification

1. After the selected V Blue file reaches working length, gauge the apical preparation with a hand file one ISO size larger.
2. After R25, gauge with an ISO 030 hand file.
3. After R40, gauge with an ISO 050 hand file.
4. After R50, gauge with an ISO 060 hand file.
5. When the gauge is snug at working length, shaping may be complete.
6. When the gauge remains loose, consider the next V Blue size and repeat the shaping and gauging procedure, if canal anatomy supports additional enlargement.

12.6 Retreatment Use Where Permitted

1. When permitted by the current NIC instructions for use, V Blue may be used to assist with the removal of gutta-percha or other compatible obturation material during retreatment.
2. Use short and controlled reciprocating movements and gentle brushing against the lateral walls when clinically indicated.
3. Withdraw frequently to clean the flutes and irrigate. Reassess whenever resistance is encountered.
4. After filling material has been removed, re-establish patency and a reproducible glide path before completing reshaping and disinfection.

12.7 Obturation Guidance

1. Complete final irrigation, drying, and apical verification before beginning obturation.
2. Select paper points and a master gutta-percha cone corresponding to the final V Blue size when dimensional compatibility has been confirmed.
3. Confirm working length, apical fit, tug-back, and radiographic fit before sealer placement and obturation.
4. Follow the instructions for use for all paper points, gutta-percha points, sealers, and obturation devices.

13. Cleaning, Disinfection, and Sterilization

NIC® V Blue 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.



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- 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 blue heat-treated NiTi alloy
Motion	Compatible reciprocating mode; never continuous rotation
Available files	R25, R40, R50
File specifications	R25 25/.08 variable regressive; R40 40/.06 variable regressive; R50 50/.05 variable regressive
Cross-section	S-shaped
Taper design	Regressive taper
Technique	Reciprocating shaping with apical gauging
Packaging	6 instruments per pack
Use	Single-use
Sterility	Non-sterile; sterilize before first use
Available lengths	21 mm, 25 mm, 31 mm



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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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