NIC® KD Blue Heat-Treated NiTi Rotary Files

Instruction For Use (Non-Sterile)

1. Product Name

NIC® KD Blue Heat-Treated NiTi Rotary Files

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

2. Product Description

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

The files are manufactured from NIC® MaxTech 6.0 blue heat-treated NiTi alloy, designed to provide high flexibility, reduced shape memory, and improved cyclic fatigue resistance for curved and complex canal preparation.

The KD Blue system provides a constant-taper Crown-Down rotary workflow with 12 size-and-taper configurations in .04 and .06 tapers, covering ISO tip sizes 15 through 40.

The file design includes a convex triangular cross-section, a non-cutting guiding tip, and a 0.8-1.4 mm maximum flute diameter to support cutting efficiency, canal-centred progression, and controlled coronal enlargement.

- Continuous clockwise rotary movement
- Crown-Down shaping technique
- 12 size-and-taper configurations
- .04 and .06 constant tapers
- ISO tip sizes 15 through 40
- MaxTech 6.0 blue heat-treated NiTi alloy
- Convex triangular cross-section
- Non-cutting guiding tip
- 0.8-1.4 mm maximum flute diameter
- 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 blue heat-treated NiTi alloy
Shank	Metal alloy
Stopper	Silicone rubber

4. Available Files

The KD Blue range includes 12 size-and-taper combinations. Files larger than 40/.04 or 40/.06 are not included in this system.

Taper	Available ISO Sizes	Motion	Available Lengths
.04	15, 20, 25, 30, 35, 40	Continuous clockwise rotation	21 mm, 25 mm, 31 mm
.06	15, 20, 25, 30, 35, 40	Continuous clockwise rotation	21 mm, 25 mm, 31 mm

5. Intended Use

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

KD Blue is intended for Crown-Down shaping where the clinician requires a broad ISO 15–40 size range and a choice between .04 and .06 tapers. File selection depends on canal anatomy, canal curvature, glide-path quality, and clinical judgment.

The .04 taper may be selected when flexibility and conservative enlargement are priorities. The .06 taper may be selected in straighter canals, mild-to-moderate curvatures, or coronal shaping when 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 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.
- 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.
- Do not apply one torque value to every size and taper. Use the file-specific torque stated in this IFU and confirm the setting against the endodontic motor manufacturer’s operating instructions.

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 a rotary KD Blue 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.
- 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 and use the next smaller instrument rather than forcing advancement.
- Use .04 taper files when flexibility and conservative enlargement are priorities in curved mid-root and apical regions.
- Use .06 taper files selectively in mild-to-moderate curvatures, straighter canals, or coronal shaping.
- Do not use .06 taper automatically in severe curvature.
- Due to MaxTech 6.0 heat treatment, the file may appear slightly curved and may be gently pre-bent to improve access. Do not straighten normal pre-curvature before use.
- Replace the file whenever stress, deformation, unwinding, or cutting deterioration is suspected.

10. Recommended Motor Settings

Use a compatible torque-controlled endodontic motor and slow-speed handpiece in continuous clockwise rotation. All KD Blue files use 500 RPM with the file-specific torque shown below.

10.1 .04 Taper Files

File	Tip	Taper	Speed	Torque	Cross Section	MFD
15/.04	0.15 mm	4%	500 RPM	0.75 N·cm	Convex triangle	1.0 mm
20/.04	0.20 mm	4%	500 RPM	0.75 N·cm	Convex triangle	1.0 mm
25/.04	0.25 mm	4%	500 RPM	1 N·cm	Convex triangle	1.0 mm
30/.04	0.30 mm	4%	500 RPM	1 N·cm	Convex triangle	1.0 mm
35/.04	0.35 mm	4%	500 RPM	1.5 N·cm	Convex triangle	1.0 mm
40/.04	0.40 mm	4%	500 RPM	1.5 N·cm	Convex triangle	1.0 mm

10.2 .06 Taper Files

File	Tip	Taper	Speed	Torque	Cross Section	MFD
15/.06	0.15 mm	6%	500 RPM	2 N·cm	Convex triangle	1.0 mm
20/.06	0.20 mm	6%	500 RPM	2 N·cm	Convex triangle	1.0 mm
25/.06	0.25 mm	6%	500 RPM	3 N·cm	Convex triangle	1.0 mm
30/.06	0.30 mm	6%	500 RPM	3 N·cm	Convex triangle	1.0 mm
35/.06	0.35 mm	6%	500 RPM	4 N·cm	Convex triangle	1.0 mm
40/.06	0.40 mm	6%	500 RPM	4 N·cm	Convex triangle	1.0 mm

Note: Motor terminology may vary by manufacturer. Confirm continuous clockwise rotation, 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. Use stainless steel K-files with an appropriate root-canal conditioner to negotiate the canal.
2. Confirm patency with a size 010 K-file.
3. Establish a smooth, reproducible glide path with at least a size 015 K-file to 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 use KD Blue rotary files without a confirmed glide path.

12.4 Crown-Down Shaping - Small Canals

1. For a small canal, begin with 30/.04 and advance passively until resistance is encountered or working length is reached.
2. When resistance occurs before working length, step down sequentially to a smaller .04 instrument until the canal can be shaped safely to length.
3. Recapitulate with a size 010 or 015 K-file between rotary instruments.
4. Irrigate between file changes and clean the flutes before reintroducing the instrument.
5. After the smaller file establishes a pathway, return to the clinically appropriate larger size when needed.

12.5 Crown-Down Shaping - Larger Canals

1. For a larger canal, begin with 40/.04 and advance passively until resistance is encountered or working length is reached.
2. When resistance occurs before working length, continue with smaller instruments until a safe pathway is established.
3. Use the larger file primarily for coronal enlargement and initial Crown-Down shaping when clinically appropriate.
4. Recapitulate with a small hand file between each rotary pass, clean the flutes, and replenish irrigant before reintroducing the file.
5. Do not force 40/.04 toward working length when resistance is present.

12.6 Taper Selection and Completion of Shaping

1. Select the final file size and taper according to canal anatomy, curvature, and apical objectives.
2. Use .04 taper files when flexibility and conservative enlargement are priorities.
3. Use .06 taper files selectively in mild-to-moderate curvatures, straighter canals, or coronal shaping.
4. Finish at the smallest size that provides adequate cleaning, taper, and apical control.
5. Recapitulate and irrigate between each rotary instrument.
6. Stop and reassess when the file no longer advances passively.

12.7 Verification, Drying, and Obturation

1. Verify the final preparation and working length.
2. Complete the final irrigation protocol and dry the canal.
3. Select compatible paper points and gutta-percha points according to the final KD Blue tip size and taper.
4. Confirm master-cone fit, tug-back, and radiographic fit before sealer placement.
5. Follow the instructions for use for all paper points, gutta-percha points, sealers, and obturation devices.

13. Cleaning, Disinfection, and Sterilization

NIC® KD 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.
- 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	Continuous clockwise rotation
Available files	15/.04, 20/.04, 25/.04, 30/.04, 35/.04, 40/.04; 15/.06, 20/.06, 25/.06, 30/.06, 35/.06, 40/.06
Taper options	.04 and .06 constant tapers
Size range	ISO 15 through 40
Cross-section	Convex triangle
Tip design	Non-cutting guiding tip
Maximum flute diameter	0.8-1.4 mm
Technique	Crown-Down rotary shaping
Packaging	6 instruments per pack
Use	Single-use
Sterility	Non-sterile; sterilize before first use
Available lengths	See product label

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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