NIC® U+ Gold Heat-Treated NiTi Rotary Files

Instruction For Use (Non-Sterile)

1. Product Name

NIC® U+ Gold Heat-Treated NiTi Rotary Files

This IFU applies to the NIC® U+ rotary shaping files and finishing files listed below.

2. Product Description

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

The files are manufactured from MaxTech 3.0 gold heat-treated NiTi alloy, designed to provide moderate flexibility, reduced rigidity, and improved resistance to cyclic fatigue for conventional root-canal preparation.

The NIC® U+ system provides a ProTaper® Gold-style Crown-Down workflow for controlled coronal shaping and progressive apical finishing. The sequence includes shaping files SX, S1 and S2, followed by finishing files F1 through F5.

- Continuous clockwise rotation
- Crown-Down shaping technique
- Progressive apical finishing sequence
- Convex triangular cross-section
- Variable taper design and safe guiding tip
- 13 mm handle for improved posterior access

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	Function	ISO Size / Taper	Recommended Setting	Available Lengths
SX	Shaping	19/.04	300 RPM / 3.0 N·cm	19 mm
S1	Shaping	18/.02	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
S2	Shaping	20/.04	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
F1	Finishing	20/.07	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
F2	Finishing	25/.08	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
F3	Finishing	30/.09	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
F4	Finishing	40/.06	300 RPM / 1.5 N·cm	21 mm, 25 mm, 31 mm
F5	Finishing	50/.05	300 RPM / 3.0 N·cm	21 mm, 25 mm, 31 mm

5. Intended Use

NIC® U+ 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 rotary motion.

6. Indications for Use

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

The shaping files SX, S1 and S2 are used for coronal and radicular shaping. The finishing files F1, F2, F3, F4 and F5 are used for progressive apical finishing according to canal anatomy and apical gauging.

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 continuous clockwise rotary motion. Do not use in reciprocating 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.
- Determine working length using radiographs and/or an apex locator.
- A slow-speed endodontic handpiece is required for rotary file use.
- Establish straight-line coronal and radicular access before using the file.
- Confirm a smooth, reproducible glide path to at least ISO 015 before rotary shaping.
- Use the recommended speed and torque settings and follow the endodontic motor manufacturer’s instructions.
- Use minimal apical pressure. Never force the files down the canal.
- Clean flutes frequently and inspect for distortion or wear.
- Irrigate, recapitulate, and re-irrigate frequently throughout the procedure, at minimum after each file.
- Use S1, S2 and SX with a brushing action on the withdrawal stroke, brushing away from furcation.
- Use finishing files F1 through F5 with a passive non-brushing action to working length.
- Do not hold any finishing file at working length for longer than approximately one second.
- Exercise caution in the apical area and around significant curvatures.
- Select the final finishing size according to canal anatomy and apical gauging. Over-enlargement increases the risk of transportation or file separation.
- 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 compatible torque-controlled endodontic motor in continuous clockwise rotary motion. Use the following settings unless the current NIC label, motor, or contra-angle instructions specify otherwise.

File Type	Motion	Speed	Torque
SX	Continuous clockwise rotation	300 RPM	3.0 N·cm
S1 and S2	Continuous clockwise rotation	300 RPM	1.5 N·cm
F1, F2, F3 and F4	Continuous clockwise rotation	300 RPM	1.5 N·cm
F5	Continuous clockwise rotation	300 RPM	3.0 N·cm

Note: Motor terminology may vary by manufacturer. Confirm the correct rotary direction, speed, torque limit, and contra-angle 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, 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

1. In the presence of a viscous chelator or lubricant, passively scout the coronal two-thirds with size 010 and 015 stainless steel hand files.
2. Continue gently until a smooth, reproducible glide path to at least ISO 015 is confirmed.
3. In restrictive canals, negotiate the apical third with size 010 and 015 hand files until they are loose at length.
4. Determine working length using a pre-operative radiograph and/or apex locator.
5. Confirm patency and verify a smooth, reproducible glide path before rotary shaping.
6. Irrigate before introducing the U+ rotary files.

12.4 Crown-Down Shaping with U+ Files

1. In the presence of sodium hypochlorite, introduce S1 into the canal and allow it to passively follow the confirmed glide path.
2. Before light resistance is encountered, use a brushing action on the withdrawal stroke to improve straight-line access and apical progression. Always brush away from the furcation.
3. Continue shaping with S1 until the depth of the size 015 hand file is reached.
4. Use S2 in the same manner as S1 until the depth of the size 015 hand file is reached.

5. Scout the apical third with size 010 and 015 hand files in the presence of viscous chelator or sodium hypochlorite until the files are loose at length.

6. Establish working length, confirm patency, and verify the presence of a smooth reproducible glide path in the apical third.

7. Use S1 with a brushing action until working length is reached.

8. Use S2 with a brushing action until working length is reached.

9. Reconfirm working length, irrigate, recapitulate, and re-irrigate, especially in more curved canals.

10. Use SX selectively with a brushing motion to improve coronal access, move the coronal aspect of the canal away from furcal concavities, create more coronal shape, or optimally shape canals in shorter roots.

12.5 Apical Finishing

1. Use finishing file F1 in a non-brushing action, with each insertion deeper than the previous insertion, until working length is reached.

2. Do not leave the file at working length for longer than approximately one second.

3. Gauge the foramen with a size 020 hand file. If the instrument is snug at length, the canal is shaped and ready for final irrigation and obturation.

4. If the size 020 hand file is loose at length, proceed to F2 and, when necessary, F3, F4 and F5 using the same passive non-brushing motion to working length.

5. Gauge after each finishing file with size 025, 030, 040 or 050 hand files respectively.

6. Stop enlargement when the selected finishing size is clinically appropriate for the canal anatomy.

12.6 Obturation Guidance

1. Complete final irrigation, drying, and apical verification before beginning obturation.

2. Select a matching ProTaper Gold®-style gutta-percha point and paper point according to the final U+ finishing file, subject to confirmed dimensional compatibility.

3. Confirm working length, cone fit, tug-back, and radiographic fit before final sealer placement.

4. Follow the respective instructions for use for all gutta-percha points, paper points, sealers, and obturation devices.

13. Cleaning, Disinfection, and Sterilization

NIC® U+ 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	Continuous clockwise rotation
Shaping files	SX 19/.04, S1 18/.02, S2 20/.04
Finishing files	F1 20/.07, F2 25/.08, F3 30/.09, F4 40/.06, F5 50/.05
Cross-section	Convex triangular
Technique	Crown-Down shaping with progressive apical finishing
Handle	13 mm handle
Use	Single-use
Sterility	Non-sterile; sterilize before first use
Available lengths	SX: 19 mm; S1–F5: 21 mm, 25 mm, 31 mm

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)

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Instruction For Use (Non-Sterile)

	Medical device that has not been subjected to a sterilization process. 5.2.7
	Autoclavable at the indicated temperature

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