NITI ROTARY FILES

(Endodontic Rotary Files — 4% Taper, 6% Taper & Variable Taper Design)

INSTRUCTIONS FOR USE (Please read carefully before use)

Doc. No: **HH/IFU/30** Approved By: **Mr. Vikram Vora** Language: **English**

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PRODUCT DESCRIPTION: Nickel-titanium rotary files for use with an endodontic motor and contra-angle handpiece. Available in 4% taper, 6% taper and variable taper (shaping and finishing) designs. Supplied non-sterile, for single use.

MATERIAL OF CONSTRUCTION: Working part — nickel-titanium alloy. Shank — brass. Stopper — silicone rubber.

INDICATIONS: Shaping and cleaning of root canals during endodontic treatment.

PROCEDURE:

1. Clean and steam sterilize the files before use.
2. Gain straight-line access and confirm working length radiographically.
3. Create a glide path with ISO 10/15 hand K-files to working length. Irrigate with NaOCl.
4. Set the motor to the speed and torque stated on the file pack.
5. **4% / 6% files:** work crown-down from larger to smaller sizes, then step up to the final apical size at working length.
6. **Variable taper files:** use the shaping files first to the coronal and middle thirds, then the finishing files to working length.
7. Use light pressure with a gentle in-and-out motion. Do not force the file. Withdraw when it stops advancing.
8. Clean the flutes and irrigate after each file. Recapitulate with a small hand file.
9. Irrigate the canal finally and proceed to obturation.

CAUTION / WARNING:

1. For use by qualified dental professionals only.
2. Single use only. Re-use increases the risk of breakage and cross-contamination.
3. Inspect each file before use; discard if bent, unwound, corroded or damaged.
4. Take extra care in curved canals and near the apex.
5. Do not immerse the whole file in NaOCl; only the working part may contact NaOCl (max. 5%, max. 5 minutes).

CONTRAINDICATIONS: Allergy to nickel or nickel-titanium alloy.

ADVERSE REACTIONS: None reported.

STERILIZATION: Steam autoclave at 134°C for 5 minutes or 121°C for 20 minutes, in a sterilization pouch. Do not use dry heat, chemical, ethylene oxide or plasma sterilization.

PACKAGING: 6 files per blister (assorted or single size), in 21, 25 and 31 mm lengths.

STORAGE CONDITIONS: Store at 5°C to 35°C in a clean, dry place away from light. Do not use if the package is damaged.

SHELF LIFE: 2 years from the date of manufacturing.

DISPOSAL: Dispose as sharp, contaminated waste per local regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

LOT Symbol for "BATCH CODE"	Symbol for "USE BY"	Symbol for "NON STERILE"
Symbol for "KEEP DRY"	Symbol for "CAUTION"	Symbol for "CONSULT INSTRUCTIONS FOR USE"
REF Symbol for "CATALOGUE NUMBER"	Symbol for "KEEP OUT OF THE REACH OF CHILDREN"	Symbol for "MANUFACTURER"
Symbol for "DO NOT USE IF PACKAGE IS DAMAGED"	35°C 5°C Symbol for "TEMPERATURE LIMITATION"	Symbol for "KEEP AWAY FROM SUNLIGHT"
MD Symbol for "MEDICAL DEVICE"	IN Symbol for "COUNTRY OF MANUFACTURE"	

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Kindly retain the instructions for use & packaging box until the complete use of the product / expiry.

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.