

# ROTOFLEX GOLD

## NiTi Rotary Endodontic File System



**Intended Use / Purpose:** RotoFlex Gold NiTi rotary files are intended for single-use preparation, cleaning, and shaping of root canals in endodontic treatment (pulpectomy). The instruments mechanically remove dentin and shape canals. Use only with endodontic electric handpieces at recommended speeds/torques.

**Device Description / Composition:** RotoFlex Gold files are spiral, nickel-titanium (NiTi) alloy rotary files (heat-treated) with color-coded handles. Product offerings include Shaper files (sizes 17/04, 20/04, 25/06, etc.) and Orifice Openers. Specifications (diameter, taper, length) are shown in the "Reference" section.

**Indications for Use:** For preparation of root canals in permanent teeth, including canals with complex anatomy, curvatures, or limited access.

### Contraindications:

- Do not use if the patient has known sensitivity or allergy to nickel-titanium alloys.
- Avoid use in very severe, abrupt canal curvatures beyond the recommended file flexibility range.

### Warnings:

- **Single-Use Only:** RotoFlex Gold files are single-use surgical instruments. Do not reuse. Reuse can lead to instrument fracture, deformation, corrosion, loss of cutting efficiency, and patient infection risk.
- **Instrument Breakage:** File separation (breakage) may occur during use, especially under excessive force or torque. Using files beyond the recommended length or speed increases fracture risk. Regularly inspect flutes for wear or defects.
- **Patient Safety:** Sharp instrument blades can cause injury or puncture. Use caution when handling files.
- **Sterility:** Non sterile files are provided and they must be sterilized before use. Do not use if packaging is opened or damaged – contaminated.
- **Dispose Sharps Safely:** After use, place files in a puncture-resistant sharp container as per regulated medical waste.

### Precautions:

- **Obtain proper access:** Ensure straight-line access and patency with manual files before rotary use. A rubber dam must be used to isolate the tooth.
- **Motor settings:** Use only endodontic handpieces at recommended settings (300 RPM, 2.0–2.5 Ncm torque for Shaper files). Do not exceed device's max speed or torque to avoid failure.
- **Irrigation/Lubrication:** Continuously irrigate canals (e.g. with NaOCl) and lubricate with EDTA or dedicated paste. Thoroughly rinse files after each use.
- **Patency:** Frequently recapitulate with a #10 K-file to maintain canal patency and prevent ledging.
- **Operating Technique:** Use gentle in-and-out pecking/brushing motions; do not force files apically. Advance files gradually. Complete each file's intended working length only once (max 1 sec at length per insertion).
- **Thermal precaution:** Allow cooling; remove debris accumulations.

**Potential Adverse Reactions:** Typical complications related to endodontic treatment may occur. These include instrument fracture/separation, canal transportation, ledging, tooth perforation, postoperative pain or swelling, soft tissue injury, bleeding or infection. Allergic reactions (e.g. to nickel) are rare but possible. Monitor patient after use and manage complications as per standard dental practice.

### Instructions for Use (Procedure):

**A) Pre-Operative:** Take diagnostic radiographs to assess canal anatomy. Classify case complexity.

Fabricate access cavity; achieve straight-line access. Ensure patency with small hand files (#10–#15 K-files).

**B) Glide Path:** Create a smooth glide path to the full working length using a #10–#15 K-file. Confirm working length radiographically or with apex locator.

**C) Rotary Shaping:** Follow sequence based on canal size (see table below). Use irrigation throughout: rinse, irrigate, recapitulate frequently.

Canal Type	Sequence
Easy Canals:	Shaper 17/04 (brushing), then 20/04, then 25/06 (final).
Moderate Canals:	Shaper 17/04 to working length, then 20/04, finish with 25/06.
Difficult Canals:	Coronal stage: 17/04, 20/04. Apical stage: advance 17/04, then 20/04, finish with 25/06.

**Torque and speed:** 300 RPM, 2.0–2.5 Ncm

**D) Apical Gauging:** After shaping, gauge apical foramen with a hand file matching last rotary size (e.g. #25 if finishing file was 25/06).

Upsize if necessary; confirm with radiograph.

### E) Obturation:

Dry canals with paper points. Follow the preferred obturation technique.

(E.g. single cone + bioceramic sealer, vertical condensation, or carrier-based obturators.)

### Sterilization and Cleaning (Pre-Use):

- All files arrive Non sterile. Clean and sterilize before use.
- Remove packaging; Rinse file under running water or saline. Use ultrasonic cleaner or enzymatic cleaner if indicated (follow device lab protocol).
- Dry completely (compressed air).
- Autoclave immediately before use: Steam sterilization at 134°C–137°C with a max temp of 140°C for a 3–5 minutes at 30 psi. Alternatively they can be autoclaved at 121°C at 15psi pressure for 15min. Use a steam gravity or pre-vacuum cyclor
- After sterilization, handle aseptically. Do not store sterilized files for long-term (use promptly).

**Storage / Shelf Life:** Store sealed packages at ambient temperature, away from moisture and direct sunlight. Do not use after the expiration date on the label. The shelf life is 5 years from the date of manufacture. Rotate stock using first-in, first-out.

### Performance Specifications:

- Materials: Nickel-Titanium alloy (heat-treated).
  - Design: Helical flutes; radial land (triangular cross-section).
  - Sizes: Diameters and tapers (e.g. 20/04, 25/06) at ISO file tips, lengths 21–31 mm.
  - Operating Range: 250–350 RPM; torque 2.0–2.5 Ncm for final shaping files.
- Compatible with standard NiTi endodontic motors (reduced-rpm recommended for small sizes).

**Risk Mitigation:** Risk of separation is minimized by single-use, controlled torque, and file design (heat-treated NiTi unwinds under extreme stress as a safety feature). Operators should avoid excessive bending or force. Infection risk is mitigated by sterilization and single use. Ensure rubber dam and careful technique to avoid perforation or damage.

**Disposal:** After use, immediately discard files into an approved sharps/contaminated medical waste container. Do not bend or break files by hand. Dispose off packaging as per local regulations. Follow national guidelines for biohazard sharps disposal.

REF -41001 : ASSORTED 21mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

REF -41002 : ASSORTED 25mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

REF -41003 : ASSORTED 31mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

REF -41004 : 21mm, 6 files of (17/04)

REF -41005 : 25mm, 6 files of (17/04)

REF -41006 : 21mm, 6 files of (20/04)

REF -41007 : 25mm, 6 files of (20/04)

REF -41008 : 21mm, 6 files of (25/04)

REF -41009 : 25mm, 6 files of (25/04)

REF -41010 : 21mm, 6 files of (30/04)

REF -41011 : 25mm, 6 files of (30/04)

REF -41012 : 21mm, 6 files of (35/04)

REF -41013 : 25mm, 6 files of (35/04)

REF -41014 : 21mm, 6 files of (40/04)















**REF - 41015** : 25mm, 6 files of (40/04)  
**REF - 41016** : 21mm, 6 files of (20/06)  
**REF - 41017** : 25mm, 6 files of (20/06)  
**REF - 41018** : 21mm, 6 files of (25/06)  
**REF - 41019** : 25mm, 6 files of (25/06)  
**REF - 41020** : 21mm, 6 files of (30/06)  
**REF - 41021** : 25mm, 6 files of (30/06)  
**REF - 41022** : 21mm, 6 files of (35/06)  
**REF - 41023** : 25mm, 6 files of (35/06)  
**REF - 41024** : 21mm, 6 files of (40/06)  
**REF - 41025** : 25mm, 6 files of (40/06)  
**REF - 41053** : 31mm, 6 files of (17/04)  
**REF - 41054** : 31mm, 6 files of (20/04)  
**REF - 41055** : 31mm, 6 files of (25/04)  
**REF - 41056** : 31mm, 6 files of (30/04)  
**REF - 41057** : 31mm, 6 files of (35/04)  
**REF - 41058** : 31mm, 6 files of (40/04)  
**REF - 41059** : 31mm, 6 files of (20/06)  
**REF - 41060** : 31mm, 6 files of (25/06)  
**REF - 41061** : 31mm, 6 files of (30/06)  
**REF - 41062** : 31mm, 6 files of (35/06)  
**REF - 41063** : 31mm, 6 files of (40/06)  
**REF - 41026** : 19mm, 6 files of (30/08)  
**REF - 41079** : PATH FILES 21mm, 6 files of (16/02)  
**REF - 41080** : PATH FILES 25mm, 6 files of (16/02)

**Packaging and References:** Available in various lengths (19 mm, 21 mm, 25 mm, 31 mm) and assortments. Minimum packaging unit: 6 pcs/pack in aluminum foil box. Refer to the reference section for full list of REF numbers and configurations.

**Caution:** US federal law restricts this product for sale by or on order of a dentist or physician.


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<b>Revision :</b>	01
<b>Date :</b>	06-04-2026

-  Symbol for "Medical Device"    
  Symbol for "Best before 6 months after opening"    
  Symbol for "Non-sterile"
-  Symbol for "Catalogue number"    
  Symbol for "Autoclave at Specified Temperature"    
  Symbol for "Do not re-use"
-  Symbol for "Nickel titanium"    
  Symbol for "Manufacturer"    
  Symbol for "Do not use if package is damaged"
-  Symbol for "Handle Right angle RA"    
  Symbol for "Silicone"    
  Symbol for "Consult instructions for use"
-  Symbol for "Keep dry"    
  Symbol for "Triangular cross section"

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. For feedback, complaint and reporting of unexpected events contact customer care.