

# ROTOFLEX GOLD



## NiTi Rotary Files

**Product Description:** Rotoflex Gold files are mechanized NiTi endodontic instruments used to prepare root canals

**Composition:** Operative portion is composed of nickel titanium alloy

**Intended Purpose/Intended Use:** For removal of dentin and shaping of root canal

**Indications for use:** It is indicated to explore, shape, clean and/or help fill a root canal system including cases with complex anatomy, abrupt curvatures, and limited access.

### Instructions for Use:

#### Step 1: Diagnosis

Take periapical X-rays to evaluate: Root canal length, width, and curvature. Classify case complexity:

- Easy: Straight, wide canals. (e.g. maxillary incisor)
- Regular: Straight/slightly curved canals. (e.g. mandibular incisor, maxillary and mandibular premolar)
- Difficult: Thin, calcified, or canals with single/double curvatures. (e.g. maxillary and mandibular molar)

#### Step 2: Access cavity and working length determination

Design access to canal openings based on tooth anatomy. Smooth internal axial walls and enlarge canal openings.

- Scout canals: Coronal 2/3: Manual/mechanical instruments.
- Coronal 1/3: Rotoflex Orifice Opener #30/08.
- Working length measurement using ISO #10 or #15 K file

#### Step 3: Preparation

##### A. Wide & Easy Canals

- Create glide path with #15 K-files, then Rotoflex-Shaper #17/04 (brushing/ pecking motion).
- Rinse after each instrument; Recapitulate and verify patency with #10 manual file.
- Shape with: Rotoflex Shaper 20/04 and 25/06 (300 RPM, 2~2.5 N.cm Torque).

##### B. Regular Canals

- Prepare from coronal to apical with Rotoflex-Shaper #17/04 (brushing/ pecking motion).
- Verify patency with #10 K-file.
- Shape with Rotoflex-Shaper 25/06 (300 RPM, 2~2.5 N.cm Torque).
- Finish shaping: 25/06

##### C. Narrow & Difficult Canals

- Coronal 2/3: Rotoflex-Shaper #17/04 → 20/04 → 25/06(if needed).
- Apically advance with #15/04.
- Verify patency with #10 K-file.
- Shape with Rotoflex-Shaper 20/04 (300 RPM, 2~2.5 N.cm Torque).
- Finish shaping: 25/06.

#### Step 4: Apical Gauging

- Gauge foramen with manual file matching last instrument size (e.g., #20, #25).
- Enlarge apically if needed (e.g., upsize file).
- Recheck apical preparation size.

#### Step 5: Obturation

Dry canals: Paper points + cannulas.

3D filling options: Single cone + bioceramic sealer (ideal for matched taper), Warm vertical condensation (complex anatomy), Carrier-based techniques (e.g., Thermafil).

**Warnings :** Files are provided non-sterile, and must be sterilized before use. This product contains nickel and should not be used for individuals with known allergic sensitivity to this material. The files are single-use only, so they are not to be reused as this can cause deformation defects (bending, stretching), fractures, corrosion, loss of colour or markings identification, etc., which would mean the instruments cannot meet the level of safety required for the intended use. Reuse increases the risk of cross-contamination and breakage. There is an increased risk of file separation when used after several disinfection or sterilization cycles

**PRECAUTIONS FOR USE :** Straight-line access is a prerequisite for proper root canal treatment, and with K-Files there is no exception. These instruments should not be immersed in a sodium hypochlorite solution. Clean files frequently during instrumentation, inspecting for any signs of distortion or wear, such as missing flutes or nicks. Irrigate frequently, recapitulate and irrigate the canal throughout the whole procedure

**CONTRAINDICATION :** Do not use in patients allergic to Nickel.

**STERILIZATION :** Products must be sterilized before use.

- 1) Rinse the device with Normal saline (0.9% NaCl) for 10 seconds;
- 2) Dry the device with a dental air gun.
- 3) Steam sterilization at 134 °C for 18 minutes

#### CAUTIONS

- 1) The file tip should not go beyond the apex while shaping the canal.
- 2) It can not work if there is any incorrect operation: use the wrong technique when operating; the angle of rotation beyond 180°; use the files without the sequence; performing the ledges; without patency and excessive force to the canal.
- 3) Frequently clean the spires; irrigate frequently and abundantly; follow the advised settings RPM - Torque. Start the procedure after scouting; Work with plenty of irrigant into the root canal.
- 4) Symbols: There is information about the manufacturer, product name, specification, color model, quantity and production date printed on the package.

**TRANSPORT :** To prevent the medical device from being damaged during transport, the use of specific racks, trays or rigid containers may be recommended. When the package is broken, it is no longer sterile. It must be cleaned, disinfected and sterilised before use.

**STORAGE AND EXPIRY :** Avoid storing in places with high temperatures, humidity and/or direct sunlight. Keep liquids away. Store at ambient temperature. Do not damage or puncture the packaging materials. This product is subject to improvement without prior notice. Apply the "first in, first out" approach to inventory management. Do not store under a germicidal lamp to prevent deterioration. The shelf life of endodontic files is 5 years

**DISPOSAL :** This product should be disposed of as medical waste. For correct disposal, always respect national laws and recommendations from authorities.

**REF :41001**

(R-Shaper Files, Triangular Cross Section) ASSORTED 21mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

**REF :41002**

(R-Shaper Files, Triangular Cross Section) ASSORTED 25mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

**REF :41003**

(R-Shaper Files, Triangular Cross Section) ASSORTED 31mm, (30/08 Opener, 17/04, 20/04, 25/04, 20/06, 25/06)

**REF :41004**

(R-Shaper Files, Triangular Cross Section) 21mm, (17/04)

**REF :41005**

(R-Shaper Files, Triangular Cross Section) 25mm, (17/04)

**REF :41006**

(R-Shaper Files, Triangular Cross Section) 21mm, (20/04)

**REF :41007**

(R-Shaper Files, Triangular Cross Section) 25mm, (20/04)

**REF :41008**

(R-Shaper Files, Triangular Cross Section) 21mm, (25/04)

**REF :41009**

(R-Shaper Files, Triangular Cross Section) 25mm, (25/04)

**REF :41010**

(R-Shaper Files, Triangular Cross Section) 21mm, (30/04)

**REF :41011**

(R-Shaper Files, Triangular Cross Section) 25mm, (30/04)

**REF :41012**

(R-Shaper Files, Triangular Cross Section) 21mm, (35/04)

**REF :41013**

(R-Shaper Files, Triangular Cross Section) 25mm, (35/04)

**REF :41014**

(R-Shaper Files, Triangular Cross Section) 21mm, (40/04)

**REF :41015**

(R-Shaper Files, Triangular Cross Section) 25mm, (40/04)

**REF :41016**

(R-Shaper Files, Triangular Cross Section) 21mm, (20/06)

**REF :41017**

(R-Shaper Files, Triangular Cross Section) 25mm, (20/06)

**REF :41018**

(R-Shaper Files, Triangular Cross Section) 21mm, (25/06)

**REF :41019**

(R-Shaper Files, Triangular Cross Section) 25mm, (25/06)

**REF :41020**

(R-Shaper Files, Triangular Cross Section) 21mm, (30/06)

**REF :41021**

(R-Shaper Files, Triangular Cross Section) 25mm, (30/06)

**REF :41022**

(R-Shaper Files, Triangular Cross Section) 21mm, (35/06)

**REF :41023**

(R-Shaper Files, Triangular Cross Section) 25mm, (35/06)

**REF :41024**

(R-Shaper Files, Triangular Cross Section) 21mm, (40/06)

**REF :41025**

(R-Shaper Files, Triangular Cross Section) 25mm, (40/06)

**REF :41026**

(R-Shaper Files, Triangular Cross Section) 19mm, (30/08)

**PACKAGING :** Minimum packaging unit: 6pcs/pack in aluminum foil box. Assortment: 1 piece of each size in a single pack

**Adverse Reaction :** None Known

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|                   |            |
|-------------------|------------|
| <b>Revision :</b> | 00         |
| <b>Date :</b>     | 29-05-2025 |

-  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.