

## Document Detail

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## Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
ENDODONTICS R&D Project Manager	Gilbert Rota	12-Dec-2018 7:19 am	GMT
ENDODONTICS R&D Platform Lead	Janine Conde	12-Dec-2018 8:09 am	GMT
ENDODONTICS Clinical Research SBU Manager	Kitty Formentin	13-Dec-2018 4:31 pm	GMT
ENDODONTICS Marketing Platform Lead	Sarah Waldmann	12-Dec-2018 1:34 pm	GMT
ENDODONTICS Regulatory Affairs SBU Manager	Thierry Utard	14-Dec-2018 8:47 am	GMT
ENDODONTICS Site Labeling team	Maxime Bayse	14-Dec-2018 9:03 am	GMT

TruNatomy™

US

*Rx Only*  
*FOR DENTAL USE ONLY*

## **DIRECTIONS FOR USE**

STERILE ENDODONTIC ROTARY FILES

### **TRUNATOMY™ INSTRUMENTS FOR ENDODONTIC TREATMENT:**

- TruNatomy™ Orifice Modifier: 020 .08 / 16mm;
- TruNatomy™ Glider 017 .02v / 21mm-25mm-31mm;
- TruNatomy™ Small 020 .04v / 21mm-25mm-31mm;
- TruNatomy™ Prime 026 .04v / 21mm-25mm-31mm;
- TruNatomy™ Medium 036 .03v / 21mm-25mm-31mm.

### **0) COMPOSITION**

The cutting part of these instruments is made of a nickel-titanium alloy.

### **1) INDICATIONS FOR USE**

The TruNatomy™ files are intended to be used in endodontic treatment for shaping and cleaning the root canal.

These instruments are intended to be used only in a clinical or hospital environment, by qualified users, following good dental practices.

### **2) CONTRAINDICATIONS**

Like with all mechanically driven root canal instruments, TruNatomy™ files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.

### **3) WARNINGS**

These files are to be used only in a clinical environment by qualified users.

This product contains nickel and should not be used for individuals with known allergic sensitivity to this material.

TruNatomy™ files are provided sterile and their reuse can increase the risk of cross contamination.

## 4) PRECAUTIONS

Like with all new products, you must take caution until you become proficient in its use. Working length determination is imperative to ensure proper instrumentation using any mechanized or hand instrument. The use of radiographs in combination with an apex locator is a recommended method of working length determination. These instruments are to be used only in a clinical or hospital environment by qualified users following good dental practice (using gloves, glasses, a mask and a rubber dam etc.). While we have implemented safeguards against possible misuse, there are several important points to remember:

- Inspect the packaging before use and do not use the instruments if the packaging is damaged;
- For optimal usage, torque controlled motors are recommended;
- All the TruNatomy™ rotary files should be used at motor speed of 500 rpm and 1.5 Ncm torque;
- Before using any instrument, make sure it is well connected to the contra-angle head;
- Use the TruNatomy™ files with no brushing action;
- Take caution in the apical area and around significant curvatures;
- These instruments should not be immersed in a sodium hypochlorite solution;
- Clean the flutes frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, dull spots;
- Frequently irrigate, recapitulate and irrigate the canal throughout the procedure, after using each file;
- TruNatomy™ files should only be used in regions of the canal that have a confirmed and reproducible glide path;
- Use the appropriate finishing files to passively follow the canal to the working length as recommended in the step-by-step instructions (part 6), and then withdraw immediately;
- The maximum preparation size for the TruNatomy™ system is given by the MEDIUM size instrument but if a larger preparation is needed we recommend refining the apical area with the necessary NiTi hand files;
- The TruNatomy™ files are intended for Single Use only (on one patient during a single procedure). The TruNatomy™ files mechanical characteristics support at least 4 canals, 35° curved (i.e. Schneider technique).

TruNatomy™ files are manufactured with a process that results in a file that has a colored appearance. Due to this proprietary processing, TruNatomy™ files may appear slightly curved. This is not a manufacturing defect. While the file can be easily straightened using only your fingers, it is not necessary to straighten the file prior to use. Once inside the canal, the TruNatomy™ file will follow the anatomy.

## 5) ADVERSE REACTIONS

This product contains nickel and should not be used for individuals with known allergic sensitivity to this material.

## 6) STEP BY STEP INSTRUCTIONS FOR TRUNATOMY™ FILES

### 6.1 Radiographic Evaluation

Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root and canal.










### 6.2 TruNatomy™ Shaping Technique

- 1) Estimate the working length using well-angulated preoperative radiographs as per 6.1.
- 2) Prepare a conservative access cavity sufficient enough to reveal all root canal orifices.
- 3) Scout coronal 2/3 of canals with a # 010 K-file in the presence of lubricant such as PROLUBE® and irrigate.
- 4) Followed by a TruNatomy™ Orifice Modifier at 500 rpm and 1.50 Ncm.  
With irrigant in canal advance the TruNatomy™ Orifice Modifier in 2-3 gentle amplitudes approximately 2-5 mm in-and-out of the canal. Repeat until the coronal third is shaped. The instrument has 7 mm of cutting flutes, which should not be exceeded beyond the canal orifice. Irrigate the canal and clean cutting flutes routinely.
- 5) Scout the whole root canal with a # 010 K-file, determine Working Length (WL) using an Electronic Apex Locator (EAL) in combination with radiographs, irrigate and confirm patency.
- 6) With irrigant in the canal create and confirm a reproducible glide path using a TruNatomy™ Glider in 2-3 gentle amplitudes approximately 2-5 mm. Irrigate and repeat until previously confirmed WL with an EAL has been reached.
- 7) ALWAYS begin shaping with the TruNatomy™ PRIME file (500 rpm / 1.5 Ncm) passively in the presence of sodium hypochlorite with no more than 2-3 gentle amplitudes approximately 2-5 mm in-and-out of the canal. Irrigate and repeat as necessary to WL.  
Upon reaching length, remove the file to avoid over-enlarging the apical foramen.
- 8) Routinely irrigate the canal and clean the files cutting flutes of debris upon removal.
- 9) If the TruNatomy™ PRIME file does not progress easily, remove, irrigate, and recapitulate with a # 010 K-file to confirm canal patency and move to the TruNatomy™ SMALL file.
- 10) Inspect cutting flutes routinely upon removal for presence of unwinding and straightening. If deformation is noted, discard and use a new TruNatomy™ file.
- 11) Advance the TruNatomy™ SMALL file passively in the presence of sodium hypochlorite with no more than 2-3 gentle amplitudes approximately 2-5 mm in-and-out and remove file. Irrigate and repeat as necessary to WL in a gentle/passive in-and-out motion (as described above) and then use the TruNatomy™ PRIME file to working length to optimize the shape\*.  
Upon reaching length, remove the file to avoid over-enlarging the apical foramen.
- 12) When the shape is confirmed, proceed with 3-D disinfection protocols.
- 13) Use dedicated TruNatomy™ paper points to dry the root canals and dedicated TruNatomy™ Conform Fit™ Gutta Percha points to obturate.

\* If the TruNatomy™ PRIME file is loose at length with no dentinal debris in the apical flutes, continue shaping with TruNatomy™ MEDIUM file.

## 7) CLEANING, DISINFECTION AND STERILIZATION

Not applicable; the TruNatomy™ instruments are intended for Single Use only.

Symbols	EN
	Single use only
	Expiry date
	Reference number
	Batch number
	Consult Instructions for use
	Sterilized by radiation
	Do not use if seal is broken
	Non-returnable if seal is broken
	Clockwise rotation

### Manufactured for:



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