Dentsply Sirona

MAILLEFER

TruNatomy™

EN

*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 prior to their reuse it is required to go through the reprocessing procedure as described in chapter 7.

## 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 1.5N cm 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;
- For the reuse of the TruNatomy™ instruments, refer to the recommended number of uses specified in chapter 7.4.

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 GLYDE™ FILE PREP 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 2-5mm. 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 2-5mm 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

**Reprocessing procedure for dental instruments.**

## I - FOREWORD

**Devices that are marked as "sterile" do not require any specific treatment before the first use. For all other devices not labelled "Sterile", cleaning and sterilization prior first use is required according to section III - STEP-BY-STEP INSTRUCTIONS part 4 to 8 of this DFU.**

These devices are not labelled "single use", re-processing of these devices should be carried out as per this DFU. For hygiene and sanitary safety purposes, these instruments must be cleaned and sterilized before each re-use to prevent any contamination.

## II - GENERAL RECOMMENDATION

1) Use only a detergent solution, with disinfecting effect, which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the detergent. Solution manufacturer. For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents.
2) For your own safety, please wear personal protective equipment (gloves, glasses, mask).
3) The user is responsible for the cleaning and sterilization of the product for the first cycle and each further usage as well as for the usage of damaged or dirty devices where applicable after sterilization.
4) It is safest for the practitioner to use our devices only once. Should our devices be reused, we recommend that they should not be used more than 5 times. After each processing they should be carefully inspected before use: the appearance of defects such as deformations (bent, unwound), breakage, corrosion, loss of colour coding or marking, indicate that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.

For our root canal shaping instruments we recommend not to exceed the following maximum number of uses;

| Type of canal | NiTi instruments |
|---|---|
| Extremely curved (>30°) or S-shaped canals | 2 canals max. |
| Moderately curved canals (10° to 30°) | 4 canals max. |
| Slightly curved (<10°) or straight canals | 8 canals max. |

5) Single use marked devices are not approved for re-use.
6) For the final rinsing step deionised water use is mandatory, whether using an automated washer-disinfector or a manual cleaning method. Tap water is permissible for the other rinsing steps.
7) Instruments with plastic handles, and NiTi instruments should not be used with Hydrogen Peroxide ($H_2O_2$) solution which is known to degrade them.
8) Only the active part of the NiTi instrument, which is in contact with the patient should be immersed in a NaOCl solution concentrate at NOT more than 5%.
9) Avoid device to dry out, prior to, or during pre-disinfection, or cleaning. Dried biological material can be difficult to remove.

10) Use only device appropriated support for reprocessing.
11) Do not use label systems or identification markers directly on the device.

## III - STEP-BY-STEP INSTRUCTIONS

| | *Operation* | *Activities* | *Warning and remarks* |
|---|---|---|---|
| 1. | Disassembling | - Disassemble the device, if applicable. | - Remove and discard silicone stops. |
| 2. | Pre-Disinfection | - Soak all devices immediately after use in a disinfection solution (We recommend the use of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner at 0.4% for a minimum of 15 minutes). Use a tray made from high density polyethylene or stainless steel. | - Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).<br>- The pre-disinfection solution should be a specific solution targeted by the supplier for pre-disinfection. It should be used at the dilution specified by the supplier. It should contain, or be combined with a proteolytic enzyme.<br>- The pre-disinfection solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. Change the pre-disinfection solution regularly i.e. When it becomes soiled, or when efficacy is diminished due to exposure to microbial loads.<br>- Do not use pre-disinfecting solutions containing Phenol or any products, which are not compatible with the devices.<br>- For visible impurities observed on instruments a pre-cleaning is recommended with a soft brush (made from either nylon, polypropylene, acrylic). Manually brush the device until visible impurities are removed. |
| 3. | Rinsing | - Abundant rinsing (at least 1 min) under running water (ambient temperature). | - Use tap water for rinsing.<br>- If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the cleaning step. |
| 4a. | Automated Cleaning with washer- disinfector | - Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts.<br>- Place the devices in the washer-disinfector and execute the defined cycle (Ao value > 3000 or, at least 5 min at 90°C (194°F)).<br>- Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%). | - Discard any devices with defects (broken, bent,…).<br>- Avoid any contact between instruments or posts when placing in the washer-disinfector use kits, supports or containers.<br>- Follow instructions and concentrations given by the manufacturer of the detergent solution.<br>- Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer.<br>- The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer.<br>- Use only approved washer-disinfector according to EN ISO 15883, maintained and validated regularly.<br>- It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with its DFU The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor. |
| **OR** | | | |
| 4b.i | Manual Cleaning assisted by an ultrasonic device | - Place the devices in a kit, support or container (made from stainless steel, polypropylene or titanium) to avoid any contact between devices.<br>- Immerse in the detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 2%), assisted by an ultrasonic device if suitable for at least 15 min. | - No visible impurities should be observed on the devices.<br>- If visible impurities are observed on the devices, the device must be manually brushed with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed.<br>- Discard any devices with defects (broken, bent, and unwound).<br>- Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution.<br>- It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with the DFU of the detergent solution manufacturer).<br>- The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor. |

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|---|---|---|---|
| 4b.ii | Rinsing | - Abundant rinsing (at least 1 min) under running water (ambient temperature). | - Use deionised water for rinsing.<br>- If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving. |
| 4b.iii | Drying | - Devices should be thoroughly dried before inspection and packaging. | - Dry with a single use non-woven cloth.<br>- Devices should be dried until visual traces of moisture are eliminated.<br>- Particular attention has to be paid to effectively dry joints or cavities within a device. |
| 5. | Inspection | - If applicable assemble the devices (including the placement of new silicon stops).<br>- Inspect the devices functionality.<br>- Visually inspect devices with naked eye under appropriate lighting (min 500 lux) and sort out those with defects. | - Dirty devices must be cleaned again.<br>- Do not re-use silicon stops.<br>- Discard devices, which show any defect as described in the General Recommendation above (point 4). |
| 6. | Packaging | - Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilization pouches”. | - Device must be double-packaged using paper-plastic pouches for steam sterilization prior sterilization. Ensure that the pouches are suitable for steam sterilization and were validated and manufactured as per ISO 11607 and EN 868-5.<br>- Use an appropriate packaging, moist-heat resistant (141°C, 286°F) and compliant with ISO 11607.<br>- Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers.<br>- For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.<br>- Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermosealer must be calibrated and qualified.<br>- Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life. |
| 7. | Sterilization | - The following sterilization cycles can be used :<br>• 132°C (269.6°F), 4 minutes;<br>• 134°C (273.2°F), 3 minutes;<br>• 134°C (273.2°F), 18 minutes.<br>We recommend a steam sterilization at 134°C / 273.2°F during 18 minutes for the purpose of de-activating potential prions. | - The instruments and posts must be sterilized according to the packaging labelling.<br>- When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer’s maximum load is not exceeded.<br>- Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer.<br>- Use only Pre-Vacuum air Removal steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer), with saturated steam.<br>- Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min.<br>- Respecting the maintenance procedure of the sterilizer is under the responsibility of the owner and should be performed following the requirements for medical devices sterilization (examples: planning of maintenance, qualification, acceptance criteria of condensate and water as per EN 285, annex 2).<br>- Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). A special attention should be paid to the packaging integrity if the sterilization cycle 134°C (273.2°F), 18 minutes was used.<br>- Store traceability records and define shelf-life according to packaging manufacturer guidelines.<br>- Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions. |
| 8. | Storage | - Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C (59 - 77°F)). | - After sterilization, the product should be manipulated with care in order to keep the integrity of the packaging (sterile barrier).<br>- Sterility cannot be guaranteed if packaging is open, damaged or wet.<br>- Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date). In case of damage, a complete rework should be performed. |

| Symbols | EN |
|---|---|
|  | Handle Right angle RA |
|  | Expiry date |
|  | Manufacturer |
|  | Consult Instructions for use |
|   | Sterilized by radiation |
|   | Reference number |
|   | Batch number |
|  | Assortment |
|   | Nickel titanium |
|   | Silicone |
|  | Do not use if package damaged |
|  | Nonreturnable if seal is broken |
|  | Clockwise rotation |
|   | Sterilizable in a steam sterilizer (autoclave) at temperature specified |

**Manufacturer**

CE
0086

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