ProTaper Gold® Treatment

EN

FOR DENTAL USE ONLY

DIRECTIONS FOR USE

A04092XXGXX03 - A04102XXGXX03 - A04112XXGXX03

PROTAPER GOLD® INSTRUMENTS FOR ENDODONTIC TREATMENT:

- **ProTaper Gold® Shaping Files (SX, S1, S2)**
- **ProTaper Gold® Finishing Files (F1, F2, F3, F4, F5)**

0) COMPOSITION

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

1) INDICATIONS FOR USE

These instruments are to be used only in a clinical or hospital environment, by qualified users.
Application field: for the removal of dentin and shaping of the root canal.

2) CONTRAINDICATIONS

As with all mechanically driven root canal instruments, ProTaper Gold® files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

3) WARNINGS

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

4) PRECAUTIONS

- Straight-line access is a prerequisite for proper root canal treatment, ProTaper Gold® files are no exception.
- Multiple use disinfection and re-sterilization cycles may lead to increased risk of file separation.
- These instruments should not be immersed in a sodium hypochlorite solution.
- Instrument reprocessing: follow the reprocessing instructions on part 7.
- Clean the flutes frequently during instrumentation, inspecting for signs of distortion or wear, such as uneven flutes, dull spots.
- Frequently irrigate, recapitulate and irrigate the canal throughout the procedure, minimally after using each file.
- ProTaper Gold® files should only be used in regions of the canal that have a confirmed and reproducible glide path. Establish a reproducible glide path using hand files, at least an ISO 015 size.

- Use the Shaping Files (S1, S2 and SX) with a brushing action on the withdrawal stroke in order to create straight line radicular access.
- Use the Finishing Files (F1, F2, F3, F4 and F5) with no brushing action.
- Use the appropriate finishing files to passively follow the canal to the working length, and then withdraw immediately.
- ProTaper Gold® files are manufactured with a process that results in a file that has a Gold appearance. Due to this proprietary processing, ProTaper Gold® 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 ProTaper Gold® file will follow the anatomy.
- Always use minimal apical pressure. Never force the files down the canal.
- For optimal usage, torque control devices are recommended.
- The ProTaper Gold® rotary files can be used at motor speeds between 250 rpm and 350 rpm. Recommended motor settings:

ProTaper Gold®		
File Size	Speed [rpm]	Torque [N•cm]
ProTaper Gold® S1 & SX	300	5.10
ProTaper Gold® S2 & F1	300	1.50
ProTaper Gold® F2, F3, F4, F5	300	3.10

The speed and torque settings indicated in the above table are for example only and may vary according to each user preferences and motor capabilities.

5) ADVERSE REACTIONS

As with all mechanically driven root canal instruments, ProTaper Gold® files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

6) STEP BY STEP INSTRUCTIONS FOR PROTAPER GOLD® 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 Access Preparation

Create straight-line access to the canal orifice(s) with emphasis on flaring, flattening, and finishing the internal axial walls.

6.3 ProTaper Gold® SHAPING TECHNIQUE

The crown down technique is the technique of choice for rotary instruments.

- Create straight-line access to canal orifice.
- In the presence of a viscous chelator (such as Glyde® File Prep root canal conditioner) passively scout the coronal 2/3 with 10 and 15 hand files. Gently work these instruments until a smooth, reproducible glide path is confirmed. Alternatively, mechanized glide path files (such as ProGlider® or PathFiles®) may be used after a 10 hand file.
- In the presence of NaOCl, “float” the S1 in the canal and passively “follow” the glide path. Before light resistance is encountered, laterally “brush” and cut dentin on the outstroke to improve straight-line access and apical progression. Always brush away from the furcation.
- Continue shaping with S1 as described until the depth of the 15 hand file is reached.
- Use the S2, exactly as described for the S1, until the depth of the 15 hand file is reached.
- In the presence of a viscous chelator or NaOCl, scout the apical 1/3 with 10 and 15 hand files and gently work them until they are loose at length.
- Establish working length, confirm patency and verify the presence of a smooth reproducible glide path in the apical 1/3.
- Use the S1, with a brushing action, until working length is reached.
- Use the S2, with a brushing action, until working length is reached.
- Reconfirm working length, irrigate, recapitulate and re-irrigate, especially in more curved canals.
- Use Finishing File F1, in a “non-brushing” action, with each insertion deeper than the previous insertion until working length is reached. Do not leave the file at working length for longer than one second.
- Gauge the foramen with a 20 hand file. If the instrument is snug at length, the canal is shaped and ready to be obturated.
- If the 20 hand file is loose at length, proceed to the F2 and, when necessary the F3, F4 and F5, with the same non-brushing motion to working length, gauging after each Finishing file with 25, 30, 40 or 50 hand files respectively.
- If necessary, use the SX with a brushing motion to move the coronal aspect of the canal away from furcal concavities and/or to create more coronal shape. SX can also be used to optimally shape canals in shorter roots.
- The ProTaper Gold® sequence is the same regardless of the length, diameter or curvature of the canal.

7) DISINFECTION, CLEANING 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”, sterilization prior first use is required according to section III - STEP-BY-STEP INSTRUCTIONS part 4 to 8 of this DFU.

For those devices that are not labelled “single use”, re-processing of the 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.

Excluded devices:

Uniclip and Mooser Calcinable plastic posts cannot be sterilized and must be disinfected by immersion NaOCl (2,5 % at least) during 5 min. at ambient temperature.

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 sterilization or disinfection 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	Stainless Steel Instruments with a diameter **≤ISO 015**	Stainless Steel Instruments with a diameter **>ISO 015**	NiTi instruments
Extremely curved (>30°) or S-shaped canals	1 canal max.	2 canals max.	2 canals max.
Moderately curved canals (10° to 30°)	1 canal max.	4 canals max.	4 canals max.
Slightly curved (<10°) or straight canals	1 canal max.	8 canals max.	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). - 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. - 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. - Do not use pre-disinfecting solutions containing Phenol or any products, which are not compatible with the devices (See general recommendations). - 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. - 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. - Place the devices in the washer-disinfector and execute the defined cycle (Ao value > 3000 or, at least 5 min at 90°C). - Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%).	- Discard any devices with large obvious defects (broken, bent,…). - Avoid any contact between instruments or posts when placing in the washer-disinfector use kits, supports or containers. - Follow instructions and concentrations given by the manufacturer of the detergent solution (see also general recommendations). - Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer. - The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. - Use only approved washer-disinfector according to EN ISO 15883, maintained and validated regularly. - 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. - 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. - If visible impurities are observed on the devices, the device must be manually brushed t with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed. - Discard any devices with large obvious defects (broken, bent, and unwound). - Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution (see also general recommendations). - 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). - The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.

4b.ii	Rinsing	- Abundant rinsing (at least 1 min) under running water (ambient temperature).	- Use deionised water for rinsing. - 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 on a single use non-woven cloth, or with a hot air drier at not more than 110°C. - Devices should be dried until visual traces of moisture are eliminated. - 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). - Inspect the devices functionality. - Inspect devices and sort out those with defects.	- Dirty devices must be cleaned again. - Do not re-use silicon stops. - 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 “Sterilisation pouches”.	- Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607. - Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing. - Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated. - Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.
7.	Sterilization	- Steam sterilisation at 134°C / 273°F during 18 min is recommended for these devices, for the purpose of de- activating potential prions.	- The instruments and posts must be sterilized according to the packaging labelling. - Place the pouches in the steam steriliser according to the recommendation given by the steriliser manufacturer. - Use only steam steriliser that are matching the requirements of EN 13060 (class B, small steriliser), EN 285 (full size steriliser). - Use a validated sterilisation procedure according to ISO 17665 with a minimum drying time of 20 min. - Respect the maintenance procedure of the steriliser given by the steriliser manufacturer. - Control the efficiency and acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). - Store traceability records and define shelf-life according to packaging manufacturer guidelines. - Shorter sterilisation 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.	- Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).

Symbols	EN
REF	Identifier of the device
LOT	Lot number
	Handle right angle RA
NiTi	Nickel Titanium
Sil	Silicone
	Clockwise rotation
134° C	Sterilizable in a steam sterilizer (autoclave) at the specified temperature
	Manufacturer
	Consult instructions for use
STERILE R	Sterilized by irradiation
	Do not use if package is damaged
	Not returnable if seal is broken
	Expiry date
CE 0086	CE mark

Manufacturer

CE 0086

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