TAPER FILE
Treatment

EN

FOR DENTAL USE ONLY

DIRECTIONS FOR USE TAPER FILE
A0409 - A0410 - A0411 - A0415

TAPER FILE instruments for endodontic treatment:
- TAPER FILE shaping files
- TAPER FILE finishing files

1) 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: shaping and cleaning of the root canal system.

2) CONTRAINDICATIONS
None known.

3) WARNINGS
This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

4) PRECAUTIONS
- Multiple use disinfection and resterilization cycles may lead to increased risk of file separation.
- These instruments should not be immersed in a sodium hypochlorite solution.
- Instrument decontamination: strictly follow decontamination instructions from the manufacturer.
- Irrigate abundantly and frequently.
- Establish a reproducible glide path using hand files, at least an Iso 015 size.
- Use in a constant rotation at a speed of 250-350 rpm with light apical pressure.
- Clean flutes frequently and check for signs of distortion or wear.
- For optimal usage, torque control devices are recommended.
- 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.

5) ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

6) STEP BY STEP INSTRUCTIONS FOR TAPER FILES

1) Create straight line access to canal orifice.
2) Always irrigate and confirm a reproducible glide path with an ISO 015 hand file.
3) Protocol of use:
   - Locate the orifice.
   - Use passively an ISO 015 hand file to resistance.
   - Use Shaping File S1 with brushing action until the same depth as the ISO 015 hand file is reached.
   - Repeat this sequence until the working length is determined with an ISO 015 hand file and reached with S1.
   - Use shaping file S2 with brushing action until the working length is reached.
   - Double check the working length.
   - Use finishing file F1 (non-brushing motion) with each insertion deeper than the previous insertion until the working length is reached.
   - Gauge the foramen with hand files.
   - Use the appropriate finishing file (F2, F3, F4, F5) with the same non-brushing motion to working length if additional enlargement is required or if foramen is larger.

   If necessary, use the SX with a brushing motion to move the coronal aspect of the canal away from the furcation and / or to create more coronal shape.

7) DISINFECTION, CLEANING AND STERILIZATION

Reprocessing procedure for dental instruments.

I - FOREWORD

For hygiene and sanitary safety purposes, all instruments must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent ones.

Instruments which are marked as “sterile” do not require any specific treatment before the first use, but have to follow this procedure for all subsequent use if not labelled as “single use”.

II - AREA OF APPLICATION

Disinfection and sterilisation before each use (except for the first use of sterile instruments) and reprocessing procedures concerning:

DESINFECTION and STERILIZATION

A. Device

A1. Instruments:

Cutting instruments, (hand and engine driven) such as:

- Endodontic instruments (files, broaches, reamers, enlargers, endodontic burs, ultrasonic inserts);
- Rotary cutting instruments (Diamond burs, tungsten carbide burs, stainless steel drills, carbon steel burs).

Root canal filling instruments (Pluggers, spreaders, compactors).
Hand instruments, clamps and Rubber Dam accessories.

A2. Accessories:
Supports, kits, instrument organisers and other accessories.

DESINFECTION ONLY

B. Filling material and calcinable plastic posts

Only chemical disinfection (no sterilisation) Gutta percha, Obturators, Uniclip and Mooser Calcinable plastic posts.

PRESENT PROCEDURE NOT APPLICABLE

C. Exclusion

- Equipment such as Motors, Apex locators and other devices with reprocessing procedures included in the individual Direction for Use.
- MTA, Glyde, TopSeal, Paper Points, Rubber Dam.

III - GENERAL RECOMMENDATION

1) Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer. For all metal instruments, 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 instruments where applicable after sterilization.
4) It is safest for the practitioner to use our instruments only once. Should our instruments be reused, we recommend to always carefully inspect them before use: the appearance of defects such as cracks, deformations (bent, unwound), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.

In any case, we recommend not to exceed the following maximum number of uses for our root canal shaping instruments:

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) The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer disinfector.
7) Tungsten carbide burs, plastic supports, hand instruments and NiTi instruments are degraded by Hydrogen Peroxide (H_2O_2) solution.

8) Only the active part of the NiTi Instruments should be immersed in a NaOCl solution at NOT more than 5%.
9) Do not use acid (pH < 6) or alkaline (pH > 8) solutions with aluminium devices. These types of devices are degraded in presence of caustic soda solutions with mercury salt.
10) The washer-disinfector is not recommended for devices made of aluminium, tungsten carbide or carbon steel.

IV - Step-by-step procedure

A. Devices

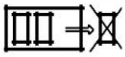
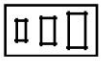
			A3. Contra Angle			
			A1. Instruments	***Following uses***		
			A2. Accessories	***First use***		
	Operation	***Operating mode***	***Warning***			
1.	Disassembling	- Disassemble the device, if required.	- Silicone stops have to be removed.		X	
2.	Pre-Disinfection	- Soak all instruments immediately after use in a detergent and disinfecting solution combined with proteolytic enzyme if possible.	- Follow instructions and observe concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on instruments). - The disinfecting solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. - Do not use disinfecting solutions containing Phenol or any products which are not compatible with the instruments (See general recommendations). - For visible impurities observed on instruments a pre cleaning is recommended by brushing them manually with soft material.		X	
3.	Rinsing	- Abundant rinsing (at least 1 min).	- Use quality water in accordance with local regulations. - If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the cleaning.		X	
4a	Automated Cleaning with washer disinfector	- Place the devices in a kit, support or container to avoid any contact between instruments or posts. - Put them in the washer disinfector (Ao value > 3000 or, at least 5 min at 90 °C).	- Discard any instruments with large obvious defects (broken, bent). - Avoid any contact between instruments or posts when placing in the washer disinfector use kits, supports or container. - Follow instructions and observe concentrations given by the manufacturer (see also general recommendations). - Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly.	X	X	X
OR						
4b	Manual Cleaning and assisted by an ultrasonic device	- Place the devices in a kit, support or container to avoid any contact between instruments. - Immerse in the disinfecting solution with cleaning properties, assisted by an ultrasonic device if suitable.	- No visible impurities should be observed on the instruments. - Discard any instruments with large obvious defects (broken, bent, and twisted). - Follow instructions and observe concentrations and time given by the manufacturer (see also general recommendations). - The disinfecting solution should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.	X	X	
5.	Rinsing	- Abundant rinsing (at least 1 min).	- Use quality water in accordance with local regulations. - If a disinfecting solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the autoclaving. - Dry on a single use non-weaved cloth, or with a drying machine or filtered compressed air.	X	X	

6.	Inspection	- Inspect devices and sort out those with defects. - Assemble the devices (stops).	- Dirty instruments must be cleaned and disinfected again. - Discard instruments which show any defect as described in the General Recommendation above. - Protect carbon steel bur with corrosion inhibitor before packaging. - For Contra Angle : lubricate the device with an adequate spray before packaging.	X	X	X
7.	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”.	- Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607.	X	X	X
8.	Sterilization	- Steam sterilisation at: 134 °C / 273°F during 18 min.	- The instruments, posts and the plastic supports must be sterilized according to the packaging labelling. - Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Use a validated sterilisation procedure according ISO 17665 - Respect the maintenance procedure of the autoclave device given by the manufacturer. - Use only this recommended sterilization procedure. - Control the efficiency (packaging integrity, no humidity, colour change of sterilisation indicators, physico-chemical integrators, digital records of cycles parameters). - Traceability of procedure records	X	X	X
9.	Storage	- Keep devices in sterilization packaging in a dry and clean environment.	- 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 validity period).	X	X	X

B. Filling material and calcinable plastic posts

	Operation	***Operating mode***	***Warning***
1.	Disinfection	- Immerse the obturation devices in NaOCl (2,5 % at least) during 5 min. at ambient temperature.	- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material (See general recommendation).

Symbols	**EN**
	Handle Right angle RA
	Autoclavable at the specified temperature
	Manufacturer
	See directions for use
	Non sterilizable
	Single use

Symbols	EN
XXXX-XXXX	min.-1 Recommended rotation speed
	Accessories
	Opened packages are not replaced
	Batch number
	Can not be sold separately
	Assortment
	Nickel titanium
	Plastic
	Silicone
	Stainless steel
	Keep away from sunlight and heat
	The upper and lower limits of temperature of use, storage and transportation
	Manufacture date
	Consult Instructions for use