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### XP-3D Shaper Instructions for Use

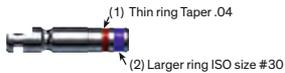
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## XP-3D Shaper

Description



Taper (1) and ISO size (2) identification



### Depth marks ▲ (in millimeters)

Available on 21 / 25 / 31 mm instruments

Example on 25 / 31 mm instruments



## Golden rules

- Speed: 800-1000 rpm
- Torque: 1 Ncm

- Prior to using the XP-3D Shaper, establish glide path to at least 15/ .02.
- In multicrooned teeth, begin with the largest canal.
- Never force the instrument.
- Irrigate copiously throughout the instrumentation protocol.

## Intended Use

XP-3D Shaper Files fit into a dental handpiece allowing the user to perform root canal debridement.

STERILE R

## Instructions for Use

- Prior to using the XP-3D Shaper (XP-S), establish glide path to at least 15/ .02. In calcified/constricted canals or complex curvatures, a glide path to 10/ .04 is recommended.
- In multicrooned teeth, begin with the largest canal. The canal should always contain irrigant.
- Insert the tip of the XP-S into the canal until resistance (Fig. 1), retract (tip loose) and start the motor.
- Use long gentle strokes to progress down to working length (WL) (Fig. 2). If WL is not reached in 5 strokes, stop, irrigate, recapitulate and proceed again. Do not use pecking motion! Never force the instrument and always keep it spinning and moving while in the canal.
- Once WL is reached, irrigate and work the instrument for 15 additional long gentle strokes to WL (Fig. 3).
- Irrigate the canal in order to eliminate suspended debris.
- Choose a gutta percha point that is tight and seats at the correct WL. If 30/ .04 is desired and does not fit, work the XP-S for an additional 5-10 strokes.
- Obturate with gutta percha and sealer. EndoSequence® BC Points™ and EndoSequence® BC Sealer™ are recommended.

Once all the canals have been shaped, proceed with the cleaning of the canals. For an optimal result, the use of XP-3D Finisher is recommended.

Once the cleaning of the canals is completed, proceed to the next phase of treatment:

Figure 1

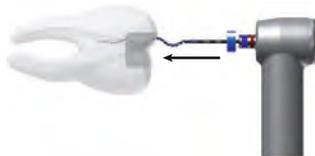


Figure 2

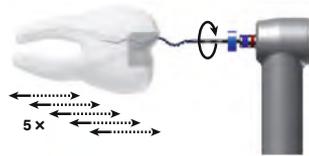
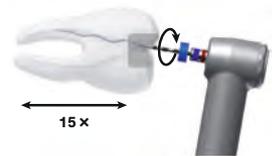


Figure 3





## Warnings



XP-3D Shaper instruments are intended for single use only, e.g. 1 tooth (up to 1 molar).  
*The reuse of instruments labeled as single use increase the risks of breakage and cross contaminations.*

- Do not soak nickel-titanium instruments more than 5 minutes in a solution of NaOCl at more than 5%.
- Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) degrades the instruments.
- Operating an Endodontic File with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, and patient burns.
- Failure to follow these instructions may cause the following: apex perforation, insufficient cleaning of the root canal, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the file.
- Irrigation with ultrasonics is recommended. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Always clean the file after every three (3) engagements. Failure to clean the file may cause the file to break or unwind causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Use a rubber dental dam while using Endodontic Files to avoid possible aspiration or swallowing of the file.
- Do not apply excessive pressure on the Endodontic Files as this could cause undesirable heat or may cause the file to fail and cause patient or user injury.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause patient or user injury.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Do not use Endodontic Files that are worn-out, dull or that exhibit "unwinding" as this could cause undesirable heat or may cause the file to fail.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to patient discomfort, injury of the patient or user, aspiration or swallowing of the Endodontic File, or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the Endodontic File is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the file to "walk out" of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the Endodontic File.
- Never force a file into a handpiece as this could cause damage to the handpiece collet.
- Eye protection must be worn to protect against ejected particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.
- This product contains nickel, a chemical known in the state of California to cause cancer, birth defects or other reproductive harm.

SYMBOL	MEANING	SYMBOL	MEANING
	Rotation speed (RPM)		Do not use if package is damaged
	Catalogue Number		Consult instructions for use
	Lot Number		Nickel Titanium
	Quantity in the package		Warning
	Sterilized by irradiation		Caution: Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device
	Expiry date		
	Do not re-use		

## Contraindications

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

## Precautions

### Sterile products - Use

1. Open the individual blister pack.
2. Extract the instrument (use of gloves imperative) and attach it to the contra-angle.
3. Use the instrument according to the protocol on front page.



4. Always check expiry date.



5. If file sterility is compromised prior to use, please clean and sterilize according to the following the protocol:

### 1. Pre-disinfection or decontamination

- Immerse the instruments as soon as possible after use in a disinfectant solution.
- Thoroughly rinse instruments in water after disinfection.

### 2. Manual cleaning & disinfection

- Soak all instruments in a disinfectant/detergent solution and, if appropriate, use an ultrasonic washing device.
- (Remove the silicone stops if necessary).

### 3. Rinsing & drying

Rinse the instruments thoroughly with clean water and dry them.

### 4. Inspection

- Check the status of instruments and eliminate those with defects.
- If the instruments are still dirty, clean them again.
- If necessary, reassemble the instruments (Mount silicone stops).

### 5. Packaging

Place the instruments in "bags for sterilization", as soon as possible after cleaning.

### 6. Sterilization\*

- Sterilize with steam at 134°C (273°F) / 2,1 bars / 18 min. for endodontic instruments and filling.
- Check the success of the sterilization cycle (cycle parameters consistent with the data validation).
- Use a physicochemical indicator for each sterilization cycle.

### \*Precautions:

- The methods of sterilization via chemiclave and hot air have not been validated.
- REPROCESSING LIMITS: A process of repeated sterilization has little effect on the instruments. The lifetime of the instruments is determined by wear and damage after use.



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