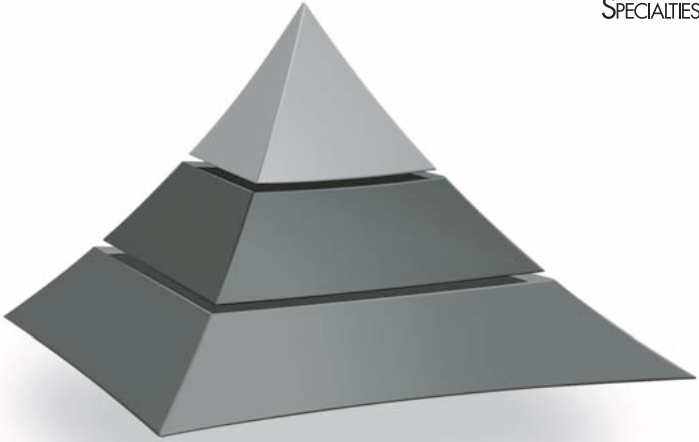


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DIRECTIONS FOR USE

ProTaper® Universal Endo System

Directions for Use

An instructional DVD is included with your system purchase. Please view this DVD, in addition to reading this booklet, to gain a complete understanding of the system and the technique. If you would like to speak with one of our staff clinicians, please call 1-800-662-1202, and we'll provide one-on-one assistance.

Indications for Use

For the removal of dentin, shaping and obturating of the root canal.

Contraindications

None known.

Warnings

- **This product contains dry natural rubber.**
- Do not use near standing water. Dropping the oven and/or motor into water may cause electric shock.
- Do not immerse the oven and/or motor into water.
- Do not expose the oven to moisture.
- Turn off and unplug when not in use.
- Do not remove the cover of the oven.
- This oven is designed for use in a dental office. Do not use in any other environment.

Precautions

As with all new products, you must exercise caution until you become proficient in its use. While we have implemented safeguards against possible misuse, there are several important points to remember:

- A slow-speed hand piece is required for rotary file use.
- Operate the hand piece at 300 RPM (revolutions per minute).
- Straight-line access is a prerequisite for proper endodontic treatment. ProTaper Universal files are no exception.
- Always utilize minimal apical pressure. Don't force the files down the canal.
- Clean file flutes frequently during instrumentation (after the file is removed from the canal).
- Frequently irrigate and lubricate the canal throughout the procedure.
- To promote the mechanical preparation objectives, take any

ProTaper Universal rotary finishing instrument to length only one time and for no more than one second.

- Exercise caution in the apical area and around significant curvatures.
- Files are single use devices. They can become less efficient after multiple uses causing undue stress to the file. This can lead to file separation.
- When instrumenting the canal, select appropriately sized instruments, as choosing an overly large file can lead to dangerous over-enlargement of the coronal portion of narrow root forms. Additionally, too large a file taken to length increases the risk of separation.
- To reduce the risk of electric shock, do not remove oven cover; there are no user-serviceable parts inside.
- This oven is intended for use in heating gutta-percha coated obturators only. Do not insert anything other than an obturator into the oven.

Patients with latex sensitivity may experience allergic reactions to gutta-percha, which contains dry natural rubber

Turning On Safe and Efficient Power

ProTaper Universal rotary instruments are used in a controlled, slow-speed rotary hand piece, thus providing the reaming action that produces a continuous tapered preparation from orifice to apex. A torque control motor, such as the Aseptico Endo DTC (model #AEU-25) included in your system, should be used.

Procedures for Using the Aseptico Endo DTC Motor*

Preset torque settings are recommended for each file series. They are given without guarantee of risk or fracture. To avoid file separation, remember torque control motors are not a substitute for proper technique.

When you remove the Endo DTC from the box, you must set the motor to accommodate the reduction contra angle you will use. To do this, turn on the power, and the motor automatically will lead you through the process. On the screen, you will see "1/8 hand piece TUL." Enter "2" for yes or "1" to go to the next hand piece selection. Simply select the hand piece you will use.

You will notice the ProTaper Universal system technique is set as a preset. Press the appropriate preset button repeatedly to cycle through the ProTaper Universal file series.

* Refer to manufacturers' directions for use for all other motors.

ProTaper Universal System Technique Steps

Refer to your Endo DTC instruction manual for more operational and maintenance procedures.

File Sterilization

Files must be sterilized before use. ANSI/ADA Specification 28 recommends:

- Scrub the instruments with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.
- Place the instruments, unwrapped, in the autoclave tray.
- Use fresh distilled or deionized water.
- Autoclave under pressure of 0.22 MNm² at 136 (± 2°) C for 30 ± 0.5 minutes

The crown down technique is the technique of choice for rotary instruments. This technique initiates in the coronal area and progresses in an apical direction. The progression of instrumentation and examination continues until you take an appropriate finishing file to working length.

The basic ProTaper Universal System sequence will be the same, regardless of the canal size.

- Create straight-line access to canal orifice.
- In the presence of a viscous chelator (such as ProLube[®] 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.
- In the presence of NaOCl, "float" the S1 into 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 the 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 NaOCl or a viscous chelator, 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.

Adverse Reactions

*Step-By-Step
Instructions*

- Use the S1, as described, until working length is reached.
- Use the S2, as described, until working length is reached.
- Reconfirm working length, especially in more curved canals.
- Use the F1 in a non-brushing action until working length is reached.
- Gauge the foramen with a 20 hand file. If this instrument is snug at length, the canal is shaped and ready to obturate.
- If the 20 hand file is loose at length, proceed to the F2 and, when necessary, the F3, F4 and F5 gauging after each finishing file with corresponding hand file.

Important Tips

- Always establish a reproducible glide path in each canal with a 15 hand file prior to rotary instrumentation.
- Lubricate files generously with a file prep such as ProLube® root canal conditioner.
- Irrigate, recapitulate and re-irrigate after using each rotary file.
- Always confirm working length.
- Take files to resistance – never force files.
- Use all ProTaper Universal rotary files in constant rotation at a speed of 300 RPM. The file will appropriately follow the canal.
- Inspect files for distortion or wear, such as uneven flutes, dull spots or bending.
- Use shaping files with a brushing action on the withdrawal stroke in order to create straight-line radicular access and to passively progress apically.
- Finishing files should follow canal passively to working length, then be withdrawn.
- Use the SX after the S1 and S2 to optimally shape canals in shorter roots, relocate the coronal aspect of canals away from furcal concavities, or to expand the shape as desired.
- In more curved canals, take any ProTaper Universal rotary finishing instrument to length only one time and for no more than one second or you may risk transportation.
- ProTaper Universal rotary files are single patient use devices.

Select the ProTaper Universal size verifier that matches the finishing file taken to working length. To set the length in this technique, set the rubber stop at your working length. Take the size verifier to working

length. The size verifier should fit passively (can easily be rotated by hand at working length up to 1/2 rotation). If it does not fit passively, the verifier may be used as a finishing file to gently enlarge the canal terminus for a passive fit. Select the obturator that matches the chosen verifier.

Always use the length calibration marks on the obturator for length determination. These calibration marks are at 18 mm, 19 mm, 20 mm, 22 mm, and 24 mm. Because gutta-percha distribution on the carrier can vary, do not attempt to set this length based on a ruler measurement of the obturator.

Preparation of the Canal

Irrigate with BioPure® MTAD® Antibacterial Root Canal cleanser according to product directions. BioPure MTAD cleanser should be the last liquid introduced into the canal before sealer is placed. Thoroughly dry the canal.

ProTaper Universal obturators should be placed only in a canal that has been thoroughly dried. ProTaper Universal absorbent points are appropriate because they conform to these instruments' predefined canal shapes.

After the canal has been dried, pick up sealer with a ProTaper Universal absorbent point measured to working length. Lightly coat the walls of the canal with the sealer to the working length. Take a dry, appropriately sized ProTaper Universal absorbent point, also measured to working length, and "wick" up any excess sealer.

It is recommended that noneugenol sealers like ThermaSeal® Plus sealer be used with the ProTaper Universal obturators' alpha phase gutta-percha. The sealer, in addition to penetrating minute canal spaces, acts as a lubricant, enhancing the flow characteristics of the centrally condensed gutta-percha.

Heating the Obturator

Heat the obturator only in the ProTaper Universal obturator oven. This oven is specifically designed to guarantee full and uniform gutta-percha heating.

Using the Obturator Oven

- Plug the oven into a 110 VAC outlet. Then turn the oven on with the power on/off switch located on the back. The yellow stand-by indicator will light up.
- Put both obturator holders in the upper position by pressing the back of the holder (arrow up) and guiding the holder up with your finger.

- After disinfecting the obturator and setting the rubber stop, place the ProTaper Universal obturator in the left obturator holder. Regardless of what working length you have determined, the rubber stop must be under the holder. Make sure the obturator is hanging straight, not at an angle. The obturator must clear all sides of the heating chamber.
- Push the holder down (arrow down) until you hear it click.
- Push the button which corresponds to the size of the ProTaper Universal obturator you wish to heat. Then push the “start left” button. The obturator is now being heated. The heating time varies depending on obturator size and is regulated automatically.
- After the first signal “beep,” the obturator is ready for use. Push the obturator holder (arrow up) and guide the holder with your finger. Take the obturator carefully out of the holder by pulling it toward you, making sure not to scrape the obturator on any part of the holder.
- You may leave the obturator in the ProTaper Universal obturator oven for up to 90 seconds after the first signal “beep.” It will keep the obturator at the appropriate temperature and ready for use. The oven will “beep” every 15 seconds to remind you that the obturator is still in the oven. After 90 seconds, the heating element will switch off automatically.
- As an extra safety precaution, after you’ve taken the obturator out of the holder, switch off the heating element by pushing the start left button again. Keep in mind that you won’t be able to switch the heating element off during the heating cycle.
- If you want to heat more obturators, you may alternate using the left and right holders to continue your work efficiently. Wait until after the signal “beeps” for the first holder, then you may immediately start to heat the other one. You will be unable to heat both sides at the same time.
- When you’re finished using the oven, use the power on/off switch located at the back of the oven to turn it off. Then unplug the oven until you are ready to use it again.

Placement of the Obturator

In teeth with multiple canals, placement of ProTaper Universal absorbent points in unfilled canals will prevent excess gutta-percha material from going into those canals.

After removing the obturator from the oven, place the obturator into the canal using a slow, smooth, continuous motion up to the stopper. The placement motion should not require any serious force. To remove the handle at the orifice level, use one finger to steady the handle while severing the shaft with a Prepi® bur, high-speed bur, or ProUltra® endo tip.

Creating Post Space

A Prepi bur or high-speed round bur can be helpful in initiating post space. Using the selected bur at 150,000 RPM to 200,000 RPM, create a “dimple” 2 mm – 3 mm into the obturated canal. Center the ‘dimple’ on the plastic carrier in cases obturated with solid core techniques. Then select an appropriately sized Pro-Post® drill. Set the motor speed to 2,000 RPM. The eccentric (angle) cutting tip will remove the plastic core and gutta-percha. Use intermittent apical pressure to create the post space. Keep the preparation parallel.

Retreatment of the ProTaper Universal Obturators

ProTaper Universal retreatment files (D1, D2 and D3) are designed to remove filling materials from the root canal prior to reshaping procedures. The technique for removing either a carrier surrounded by gutta-percha or gutta-percha alone is the same.

General Tips

- Always begin with a well-angulated set of radiographs.
- A good understanding of the anatomy is critical to success.
- Obtain good straight-line access to the canals.
- Clinically assess the obturation material.
- Heat and friction will help to remove obturation material.
- Throughout the procedure, remove the instruments, inspect and clean the flutes. Then re-insert and continue to auger material out of canal.
- Recommended speed for the ProTaper Universal retreatment instruments is 500 – 700 RPM for gutta-percha and carrier based obturators. Use 300 RPM to remove paste fillers .

Retreatment Technique

- Establish a pilot hole using small sized stainless steel hand files with an appropriate solvent, heat carrier or ultrasonic instrument.
- Without engaging dentin, gently press the spinning D1 into the obturation material.
- Use the D1 to remove the obturation material from the coronal 1/3.
- Next, use the D2 to progressively remove material from the middle 1/3.
- When appropriate, use the D3 to remove obturation material from the apical 1/3.
- Remove the files frequently and inspect flutes. Continue as long as obturation material is visualized between the cutting blades.

- Use hand files with a solvent to remove obturation materials from the apical 1/3 when encountering intricate anatomy.

Oven Cleaning Instructions

Clean oven after each use. Any gutta-percha remaining on the holder or in the heating chamber may be effectively removed with Orange Solvent (generic dental solvent) or any cotton pledget.

Oven Technical Specifications

Voltage rating: 110 VAC, 50/60 Hertz, range of the supply voltage +/- 10%, Fuse 2 Amps Slow.

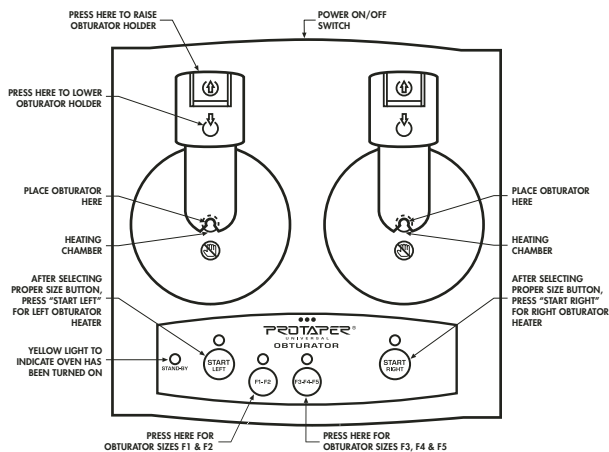
Explanation of Marking Symbols

Alternate current 

Power On 

Power Off 

Caution, Hot Surface 



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Their Satisfaction.*

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Rx only

For Dental Use Only



Shelf Life



Non-Returnable If Opened



See Directions For Use

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