ProTaper Ultimate™

EN

FOR DENTAL USE ONLY
FOR PROFESSIONAL USE ONLY
STERILE – STERILIZED BY RADIATION
LIABLE FOR REPROCESSING

INSTRUCTIONS FOR USE

REUSABLE STERILE ENDODONTIC INSTRUMENTS

0) INDICATIONS FOR USE

- The products are indicated for treatment of endodontic disease.
- Intended purpose: Engine-driven instrument intended for root canal preparation (glide path, shaping and debridement of the root canal).
- Endodontic instruments are to be used only in a clinical or hospital environment, following good dental practice, by qualified dental professionals such as general practitioners as well as Endo specialists (Endodontist) and Dental Assistants.
- Instruments shall be used in combination with an endodontic motor (manually in severe curvatures).

1) CONTRAINDICATIONS

None.

2) CONTENT, COMPOSITION AND COMPATIBLE DEVICES

ProTaper Ultimate™ instruments are made of three main components: the working part made of a nickel-titanium alloy, a colored silicone stopper (except for instrument SX) and a plated brass shank with a colored ring (except for instrument SX).
The files are manufactured with a process that results in a file that has a colored appearance.
Due to this proprietary processing, the 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 file will follow the root canal anatomy.
The ProTaper Ultimate™ range comprises following endodontic instruments:

Code **xx-length** **y-file size** **z-quantity per blister**	**Product**	**ISO XXX YYYv** **XXX-ISO size** **YYY-taper size** **v-variable taper**	**Available lengths**	**Packaging and content**
B ST PULR z 19 0SX	ProTaper Ultimate™ SX	ISO 020.003v	19 mm	Blister with 6 instruments (sterile)

				Blister with 3 instruments (sterile)
B ST PULR z xx 0SL	ProTaper Ultimate™ SLIDER	ISO 016.002v	21/25/31 mm	Blister with 6 instruments (sterile)
				Blister with 3 instruments (sterile)
B ST PULR z xx 0SH	ProTaper Ultimate™ SHAPER	ISO 020.004v	21/25/31 mm	Blister with 6 instruments (sterile)
				Blister with 3 instruments (sterile)
B ST PULR z xx 0F y	ProTaper Ultimate™ FINISHER	F1: ISO 020.007v F2: ISO 025.008v F3: ISO 030.009v	21/25/31 mm	Blister with 6 instruments (sterile)
				Blister with 3 instruments (sterile)
B ST PULR 6 xx yyy	ProTaper Ultimate™ FINISHER	FX: ISO 035.012v FXL: ISO 050.010v	21/25/31 mm	Blister with 6 instruments (sterile)
B ST PULR 5 xx SQE	ProTaper Ultimate™ Sequence	SLIDER: ISO 016.002v SHAPER: ISO 020.004v F1: ISO 020.007v F2: ISO 025.008v F3: ISO 030.009v	21/25/31 mm	Blister with 1 instrument of each instrument (sterile)
B DD PULR 525 SQE	ProTaper Ultimate™ Demo Pack	SLIDER: ISO 016.002v SHAPER: ISO 020.004v F1: ISO 020.007v F2: ISO 025.008v F3: ISO 030.009v	25 mm	Blister with 1 instrument of each instrument (sterile)

- Torque control devices ensure optimal usage.
- Use with endodontic motors in a constant rotation at a speed of 400 rpm.
- Set torque at: 4 to 5.2 Ncm
- Lubricants such as NaOCl, EDTA, ProLube, Glyde™ shall be used.
- The use of radiographs in combination with an apex locator and a tool for adjusting the silicon stopper to the correct working length is the appropriate method of working length determination.

3) WARNINGS

- Strictly follow this Instruction for Use and the General Processing Instructions For Endodontic Products (see section 8) to minimize following risks to the device, the patient and/or the user:
  - Breakage of instrument
  - Cross-contamination
  - Heat generation due to insufficient lubrication and irrigation
  - Swallowing of working part of the instrument
  - Toxic or allergic reactions caused by processing residues
- Similar to all machine-driven root canal instruments, ProTaper Ultimate™ instruments should not be used in a root canal with an abrupt apical curvature due to heightened risk of separation. In this case, pre-curved hand files should be used in the apical region.

4) PRECAUTIONS

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- Use a rubber dam system during the endodontic procedure.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- Inspect the packaging before use and do not use the instruments if the packaging is damaged.
- Do not use the instruments after expiration date.
- Check the instrument before each use for signs of defects such as deformations (bent, unwound), breakage, corrosion, damaged cutting edges, loss of color coding or marking. With these indications the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Before using any instrument, make sure it is well connected to the contra-angle head.
- Check instrument and clean working part frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, dull spots. With these indications that the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Instruments should not be fully immersed in a sodium hypochlorite solution (NaOCl). Only the working 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%.
- Exercise caution in the apical area and in canals that divide, and/or exhibit abrupt curvatures or recurvatures.
- Irrigate abundantly and frequently the canal throughout the procedure and after each instrument used (according to good dental practices)
- Always use minimal apical pressure. Never force the files down the canal.
- When instrument does not easily progress, clean and inspect the cutting flutes, then irrigate, recapitulate with a manual file and reirrigate.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:
    - Use a new file and discard it after the canal was treated (single canal use).
    - Use manual instead of rotary files.
    - Use small size, flexible or/and NiTi files (this will help avoid canal transportation).
    - Visually inspect the working part for all the defects listed in the former paragraph during use (i.e after each wave).
    - Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

5) ADVERSE REACTIONS

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

6) STORAGE CONDITIONS

Keep products in a dry and clean environment, away from sources of moisture and direct sunlight.

7) STEP BY STEP INSTRUCTIONS

All ProTaper Ultimate™ files have been validated to be used at 400 rpm and 4-5.2 Ncm torque.
The ProTaper Ultimate™ instruments can be used with an outward brushing motion in all canals, especially those canals that exhibit an irregular cross-section, or with a light inward pecking motion to progressively advance toward the working length (WL).
Always cradle the handpiece in the webbing between the thumb and index finger. Avoid pushing; rather, let the files passively progress and follow the Slidepath.

1) Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root and its canal(s).
2) Prepare an access that enables the easy identification of each canal orifice.
3) The auxiliary shaping file, SX, may be used when there is restrictive space, or to pre-enlarge the body of a canal, or to relocate the coronal-most aspect of a canal away from an external root concavity.
4) In the presence of a lubricant, select the Slider and PASSIVELY follow the canal, in one or more passes, to its terminus. Determine WL using an electronic apex locator in combination with a radiographic image, then confirm patency.
5) If the Slider will not easily reach the canal terminus, select a small-sized manual Stainless Steel (SS) hand file. In the presence of a lubricant catheterize this canal, establish working length, confirm patency, and verify the Slidepath. Now, repeat step #4 above.
6) In the presence of NaOCl, select the Shaper and advance along the Slidepath, in one or more passes, until the WL is reached.
7) Upon removing the Shaper, irrigate, EndoActivate to break up debris and move it into solution, then re-irrigate to liberate this debris.
8) Reconfirm WL, especially in more curved canals.
9) Select the FINISHER F1 (020.07) and passively follow the canal to the WL, in one or more passes. Remove and inspect its apical flutes. When loaded with dentinal debris, the preparation is finished.
10) If the FINISHER F1 is loose at length and its apical flutes are not loaded with debris, select the FINISHER F2 (025.08) and use this file in the same manner described above for FINISHER F1.
11) If the FINISHER F2 is loose at length and its apical flutes are not loaded with debris, select the FINISHER F3 (030.09) and use this file in the same manner described above for FINISHER F1 and F2.
12) Upon removing any given file, clean and inspect its cutting flutes, irrigate, recapitulate with either a size 10 file or Endo Activator to break up debris, then re-irrigate.
13) Inspect the file's cutting flutes upon removal for the presence of unwinding, straightening or stretching. If deformation is noted, discard and use a new ProTaper Ultimate™ file.
14) The preparation is finished when the apical extent of any Finisher is loaded with debris, and the correspondingly sized GPMC or Size Verifier fits at the WL.

Use the auxiliary Finishers in larger and straighter canals only, such as maxillary central incisors, some palatal or distal canals of molars, or when there is a pathologic or iatrogenic defect:

15) Select either a mechanically driven or manual auxiliary file, FINISHER FX (035.12), when working length is established and patency is confirmed. Use this stand-alone file directly and passively to follow the canal to the WL using the same technique as described above. Remove and inspect its apical flutes. When loaded with dentinal debris, the preparation is finished.
16) If the FINISHER FX is loose at length and its apical flutes are not loaded with debris, select either a mechanically-driven or manual auxiliary FINISHER FXL (050.10) and use this file in the same manner described above for FINISHER FX.
17) The preparation is finished when the apical extent of any auxiliary Finisher is loaded with debris, and the correspondingly-sized GPMC or Size Verifier fits at the WL.

8) HYGIENE, DISINFECTION, CLEANING AND STERILIZATION

- Please follow the General Processing Instructions For Endodontic Products (https://www.dentsplysirona.com/en/service-contact/ifu.html) for the disinfection, cleaning and sterilization steps.
- Do not re-use silicone stops. Remove and discard silicone stops after each use.
- Products shall be disposed according to local regulations for the safe disposal of sharp and contaminated devices.

9) ADDITIONAL INFORMATION

- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
- Sterility cannot be guaranteed if packaging is open, damaged or wet.
- To get a free printed copy of IFU please see section “Get a print copy of IFU” on website https://www.dentsplysirona.com/en/service-contact/ifu.html.
- Explanation of non-harmonized symbols for IFUs and labels, see IFU Symbols (https://www.dentsplysirona.com/en/service-contact/ifu/ifu-symbols.html).

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