

DIRECTIONS FOR USE

COMPOSITION

The instrument is made of an Annealed Heat Treated (AHT) nickel-titanium alloy. All files are variable tapered.

Channels®PT™ Platinum Heat-Treated Indications for Use

These files are used in endodontics for the removal of dentin and root canal shaping. It is compatible with most rotary file systems, electric motors and hand pieces.

Contraindications

- Like all mechanically driven endodontic instruments they should not be used in cases with very severe and sudden curvatures.
- This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

Warnings

- A rubber dam system should be used.
- The Channels®PT™ Platinum Heat-Treated files are non-sterile and must be sterilized before patient use.
- Do not use the Channels®PT™ Platinum Heat-Treated file in a traditional rotary hand piece.
- Rotary motors: The Channels®PT™ Platinum can be used in a clockwise rotary motor but not in the reciprocating motor, which moves in the counter-clockwise direction.

Precautions for Use

As with all products, use carefully until you become proficient with use. Always determine working length using radiographs and/or apex locator to properly use rotary files.

Important points to remember:

1. Use only in an electric motor and hand piece designed for rotary file instruments.
2. Straight-line access is imperative for proper rotary file use and endodontic treatment.
3. Do not force the files down canals, use minimal apical pressure.
4. Clean the flutes frequently and at least after removing the files from the canal.
5. Irrigate and lubricate the canal frequently throughout the procedure.
6. Take each rotary file to length only one time and for no more than one second.
7. In apical areas and curved canals exercise caution.

8. Channels®PT™ Platinum Heat-Treated files are single patient use devices.

9. Reuse: Once file is used do not reuse. If a file is reused and used on a different patient infection can be introduced. Performance of the file can also be reduced.

10. When instrumenting the canal, do not over enlarge the coronal portion of the canal.

11. Too large a file taken to length increases the risk of canal transportation and file separation.

12. Channels®PT™ Platinum Heat-Treated files undergo a proprietary Annealed Heat Treatment (AHT) NiTi which increases cyclic fatigue resistance and torque strength. With this proprietary processing, Channels®PT™ Platinum Heat-Treated files may be slightly curved. This is not a manufacturing defect. While the file can be easily straightened with your fingers, it is not necessary as once they are inside the canal, Channels®PT™ Platinum Heat-Treated files will follow and conform to the natural canal anatomy and curvatures.

Adverse Reactions

- Device fracture/breakage
- Infection
- Complications usually associated with endodontic procedures including:
 - Pain
 - Instrument fracture/breakage
 - Soft tissue damage/bleeding

INSTRUCTIONS FOR USE

Sterilization

Files must be cleaned and sterilized before use.

- Scrub the instruments with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.
- Place the instruments, unwrapped, in an autoclave tray.
- Use fresh distilled or deionized water.
- Insert in a steam gravity cycle autoclave at 276° F (plus or minus 35° F) for 20 minutes.
- Channels®PT™ Platinum Heat-Treated files are for single patient use.
- Used files should be disposed of in a Biohazard Sharps container.

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Electric Handpiece

The Channels@PT[™] Platinum Heat Treated file can only be used in an electric hand piece and motor designed for rotary files. See manufacturer specifications.

Channels@PT[™] Platinum Heat Treated Straight-Line Access and Glide Path Formation.

- Prepare straight-line access to canal orifice.
- With lubrication in the canal form a glide path with a size #10 and #15 hand files or mechanical glide path 2/3 down the length of the canal.

Channels@PT[™] Platinum Heat Treated Size Selection: G1, G2, C1, C2 and C3 Files

- Established canal patency by taking #10 1mm past working length.
- Take a #15 hand file to working length. Shape and Finish Canal.
- Fill chamber with EDTA liquid
- Take G1 to working length. Rinse with EDTA liquid.
- Recapitulate #10 hand file to working length.
- Take G2 to working length. Rinse with EDTA liquid.
- Recapitulate #10 hand file to working length.
- Take C1 to working length.
- Rinse with EDTA liquid.
- Recapitulate #10 hand file to working length.
- If a larger file is needed then use C2 or C3.
- Disinfect and obturate canals with gutta percha points.
- Curved/Narrow/Long Canals Glide Path in Coronal 2/3.
- Fill chamber with EDTA liquid.
- Take #10 hand file 2/3 down canal
- Fill chamber with EDTA liquid.
- Take GX tip size 19 to length of hand files form Glide Path in Apical 1/3.
- Fill chamber with EDTA liquid.
- Take #10 hand file to estimated working length.
- Establish working length with Apex Locator using hand file or X-ray.

Optional Steps:G1, G2, C1, C2 and C3 Files

- Established canal patency by taking #10 1mm past working length.

- Take a #15 hand file to working length Shape and Finish Apical 1/3.
- Fill chamber with EDTA liquid.
- Take G1 to working length. Rinse with EDTA liquid.
- Recapitulate #10 hand file to working length.
- Take G2 to working length. Rinse with EDTA liquid.
- Recapitulate #10 hand file to working length. Take C1 to working length.
- Rinse with EDTA liquid. Recapitulate #10 hand file to working length.
- If a larger file is needed then use C2 or C3.
- Disinfect and obturate canals with gutta percha points.

Safe Unwinding

- As a safety feature the files are designed to unwind.

Channels@PT[™] Platinum Heat Treated Canal Shaping and Cleaning: G1, G2 and GX Files

- With lubricant in the canal and with light apical pressure take the G1 17/.06 into the canal and follow the glide path using an in-and-out motion while laterally brushing the dentin on the outstroke to enhance the straight-line access of the canal.
 - Continue shaping with the G1 until resistance is met or 2/3 down the canal is reached.
- Then use the G2, in the same way until resistance is met or 2/3 down the canal is reached.
- Switch between the G1 and G2 following the glide path using the same in-and-out as described for both files until 2/3 down the canal is reached.
- Now that the coronal 2/3 of the canal is shaped, form a glide path with the size #10 and #15 hand files or mechanical glide path files into the apical 1/3.
- Establish working length with radiographs and/or an apex locator. Then confirm patency by taking the #10 hand file 1mm past the working length.
- Then, using the same motion as before, switch between the G1 17/.06 and G2 17/.04 until G2 reaches the working length.
- If a larger coronal shape is desired, use the GX 25/.12 at any time after the coronal 2/3 is shaped.

Completing Canal Shaping and Cleaning: C1,

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C2, C3, C4 Files.

- With lubricant in the canal and with light apical pressure complete canal shaping and cleaning by taking the C1 20/.06 down the canal until the working length is reached.
- Apically gauge the foramen at the working length with a #20 hand file. If the #20 hand file is snug at the working length, the canal is shaped and ready to obturate.
- If the #20 hand file is loose, take the C2 25/.06 to the working length, then gauge with a #25 hand file. When necessary, the C3 30/.06 or C4 40/.06 may need to be used.

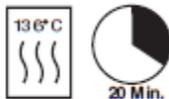
Obturation of Canal Systems

- When using a thermal carrier system, use size verifiers to determine the proper sized carrier.
- When using a master gutta percha cone that matches the largest file taken to length, remember sometimes you may need to drop down in cone tip size if the corresponding gutta percha to your final rotary file does not go to length.

Speed and Torque

- Use the same hand piece with the same speed and torque settings you are currently using with your rotary system. Or if you wish, you can use all **Channels@PT[™] Platinum** rotary files at the following speed and torque settings:

Speed	Torque
300-500 rpm	300 g-cm



Autoclave for 20 minutes
at 136°C +/- 2°C
(276.8°F +/- 35.6°F)


Consult IFU before use
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