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## Rotary Files Niti Endo

# DSI ApexFile Gold



## INSTRUCTIONS FOR USE

### INDICATIONS FOR USE

DSI ApexFile Gold for the removal of dentin and shaping of the root canal.

SHAPING FILES (SX, S1, S2)

FINISHING FILES (F1, F2, F3)

### CONTRAINDICATIONS

As with all mechanically driven root canal instruments, ApexFile Gold should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

### WARNINGS

Rotary files are non-sterile products and must be sterilized before use. This file contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

### PRECAUTIONS

As with all new products, you must exercise caution until you become proficient in its use. Length determination is imperative to ensure proper instrumentation using any rotary or hand instrument. The use of radiographs and an apex locator are two acceptable methods of length determination. These instruments are to be used only in a clinical or hospital environment by qualified users following good dental practice (using gloves, glasses and a dental dam etc.). While we have implemented safeguards against possible misuse, there are several important points to remember:

1. A slow-speed handpiece is required for rotary file use.
2. Operate the hand piece at a speed of 300 RPM (Revolutions Per Minute).

<b>DSI ApexFile Gold</b>		
File Size	Speed [rpm]	Torque [g/cm]
S1 & SX	300	520
S2 & F1	300	150
F2, F3	300	310

See motor and contra-angle requirements per motor manufacturer specifications.

3. Straight-line access is a prerequisite for proper root canal treatment, DSI ApexFile Gold are no exception.
4. Always use minimal apical pressure. Never force the files down the canal.
5. Clean the flutes frequently during instrumentation, inspecting for signs of distortion or wear, such as uneven flutes, dull spots.
6. Frequently irrigate, recapitulate and irrigate the canal throughout the procedure, minimally after using each file.
7. Use Shaping files with a brushing action on the withdrawal stroke in order to create straight-line radicular access and to passively progress apically.
8. Finishing files should follow the canal passively to working length then be withdrawn. To promote the mechanical preparation objectives, take any ProTaper Gold® finishing instrument to length only one time and for no more than one second, to avoid transportation.
9. Exercise caution in the apical area and around significant curvatures.
10. 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 file separation.
11. Use the SX after S1 and S2 to optimally shape canals in shorter roots, relocate the coronal aspect of canals away from furcation concavities, or to expand the shape as desired.
12. ApexFile Gold rotary files should only be used in regions of the canal that have a confirmed and reproducible glide path.

DSI ApexFile Gold are manufactured with a process that results in a file that has a gold appearance. Due to this proprietary processing, DSI ApexFile Gold 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 ApexFile Gold will follow the anatomy.

#### **ADVERSE REACTIONS**

None known.

#### **STEP BY STEP INSTRUCTIONS**

DSI ApexFile Gold – rotary files are single patient use instruments.

Recommended File Disposal: Place used files in a Biohazard Sharps container.

## **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.
- Steam Autoclave at 276.8°F (136°C) (plus or minus 3.6°F (2°C)) for 20 minutes.

## **INSTRUCTIONS FOR FILES**

The crown down technique is the technique of choice for rotary instruments.

- Create straight line access to canal orifice.
- In the presence of a viscous chelator passively scout the coronal 2/3 with 10 and 15 hand files. Gently work these instruments until a smooth, reproducible glide path is confirmed. Alternatively, mechanized glide path files may be used after a 10 hand file.
- In the presence of NaOCl, “float” the S1 in 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 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 feel is reached.
- In the presence of a viscous chelator or NaOCl, 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.
- Use the S1, with a brushing action, until working length is reached.
- Use the S2, with a brushing action, until working length is reached.
- Reconfirm working length, irrigate, recapitulate and re-irrigate, especially in more curved canals.
- Use Finishing File F1, in a “non-brushing” action, with each insertion deeper than the previous insertion until working length is reached. Do not leave the file at working length for longer than one second.
- Gauge the foramen with a 20 hand file. If the instrument is snug at length, the canal is shaped and ready to be obturated.
- If the 20 hand file is loose at length, proceed to the F2 and F3, with the same non-brushing motion to working length, gauging after each Finishing file with 25, 30, 40 or 50 hand files respectively.
- If necessary, use the SX with a brushing motion to move the coronal aspect of the canal away from furcal concavities and/or to create more coronal shape. SX can also be used to optimally shape canals in shorter roots.
- The ApexFile sequence is always the same regardless of the length, diameter or curvature of the canal.

## OBTURATION OF CANAL SYSTEMS

- Prior to obturation, the smear layer can be removed and a final rinse can be performed with Q-Mix and an activated irrigation technique such as the Endo Activator.
- Use a warm obturation method such as Universal obturators to encourage a dense 3D filling of the root canal system.
- A Universal Obturator of the same tip/taper as the last file taken to length can be used to obturate the canal. Rely on size verifiers to determine proper fit and length control of filling materials.

## PACKAGING

Each package contains 6 pieces

Type	19.0	21.0	25.0	31.0
Shaping SX	AFGOLD-19SX	AFGOLD-21S1	AFGOLD-25S1	
Shaping S1		AFGOLD-21S2	AFGOLD-25S2	
Shaping S2		AFGOLD-21S1	AFGOLD-25S1	
Finishing F1		AFGOLD-21F1	AFGOLD-25F1	
Finishing F2		AFGOLD-21F2	AFGOLD-25F2	
Finishing F3		AFGOLD-21F3	AFGOLD-25F3	
Assorted		AFGOLD-21SX-F3	AFGOLD-25SX-F3	AFGOLD-31SX-F3

## SYMBOLS



Consult instructions for use



Single use only



Caution, consult accompanying documents



Manufacturer



Temperature limit



Catalogue number



Keep away from sunlight



Batch code



Keep dry



Use by



Sterilize before use. Non-sterile product. Autoclave before use  
134°C/ 20 min



Date of Manufacture

*Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.*

*The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.*