

INTENDED USE

For endodontic (root canal) treatment

INDICATION

- 1) Before using **Dia-X_{File}**, check if it has been stored in a clean condition.
- 2) Check for any noticeable external damage and make sure there is no dirt, dust, or any foreign substance on the file

DIRECTIONS FOR USE

Application Method

- 1) When enlarging the root canal using **Dia-X_{File}**, start from DX and gradually enlarge D1, D2, D3, D4 and D5 (The sequence from DX to D5 is not standardized.)
- 2) Do not use the file for any other purposes.
- 3) Replace files if and when dropped on the floor or physically impacted.
- 4) If corrosion or a crack is observed, stop using immediately and replace.

STORAGE & MAINTENANCE

- 1) Cleaning (Reference. Table1.) & Sterilization
 - Soak the file in water to remove any chemical or other substances before wiping with alcohol. Repeat until foreign substances are completely removed.
 - When using an autoclave to sterilize, files must be autoclaved at 134 °C for at least 4 minutes and then dried at 20 minutes.
- 2) Examination
 - Examine closely after the file is sterilized.
- 3) Store at room temperature.

Table 1.

| INSTRUCTIONS | | | |
|---------------------------------|---|---|---|
| Point of use: | Remove foreign substances with disposal cloths or papers. | | |
| Containment and transportation: | No particular requirements | | |
| Preparation before cleaning: | Enzymatic Detergent should be diluted with water. | | |
| Cleaning: Automated | Material | Enzymatic detergent, Tap water, Purified water, automatic cleaner | |
| | Step | Procedure | Descriptions |
| | 1 | Pre wash | Wash the inoculated Dia-X_{File} to cold softened tap water for 30 seconds. |
| | 2 | Enzyme soak | Soak diluted medizyme (complex enzyme detergent) for 3minutes. |
| | 3 | Rinse | Rinse the Dia-X_{File} in tap water for 30 seconds, and repeat one time. |
| | 4 | Detergent wash | Wash the Dia-X_{File} with diluted Medizyme at 40°C ~ 45°C for 3minutes in ultrasonic cleanser. And then rinse the Dia-X_{File} with tap water for 30seconds three times. |
| | 5 | Purified Water Rinse | Wash the Dia-X_{File} with purified water at 40°C ~ 45°C for 3minutes in ultrasonic cleanser. This cleaning process is repeated two times more. |
| 6 | Dry | Dry at 90°C(±10°C) for 15~20 minutes with hot air. | |

| | Material | | Enzymatic Detergent, Alcohol, Tap water, Purified water, Sonicaator |
|----------------------------------|---|----------------------|---|
| | Step | Procedure | Descriptions |
| Cleaning: Manual | 1 | Remove Soil | Completely submerge the test sample (Dia-X_{File}) in diluted Medizyme (complex enzyme detergent) and allow to soak for 20 minutes. Scrub using a soft-bristled or nylon brush until visible soil (microorganisms) has been removed. |
| | 2 | 1st Rinsing | Rinse the Dia-X_{File} with tap water for 3 minutes to remove Medizyme (complex enzyme detergent). |
| | 3 | Ultrasonic cleaning | Wash the Dia-X_{File} with diluted medizyme (complex enzyme detergent) for 10 minutes in ultrasonic cleanser. |
| | 4 | 2nd Rinsing | Wash the Dia-X_{File} with purified water for 3minutes in ultrasonic cleanser. This cleaning process is repeated three times more. |
| | 5 | Alcohol disinfection | Soak the Dia-X_{File} in alcohol(70%) for 30 seconds, and the wipe Dia-X_{File} with dust absorbent. Inspection and Function Testing: |
| Inspection and Function Testing: | 1. Check the cleaned Dia-X_{File} holder. 2. Check for any foreign substances that become attached to the Dia-X_{File} Body. 3. Check the connection between the body and the 4. Check the Dia-X_{File} for possible cracks or damages as a defective may cause injuries to patient. 5. Check the connection between the protector and the Dia-X_{File} | | |
| Packaging: | No particular requirements Dia-X_{File} can be easily cracks and corrosion | | |
| Sterilization: | Autoclave, minimum 134 °C for 4 minutes | | |
| Storage: | keep away from any place where products may be damaged. | | |

CAUTION

- 1) Files must be sterilized before use.
- 2) Do not use in dry root canals.
- 3) Do not apply too much force when inside a root canal.

Note1 : 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.

Note 2. The device can be used Transient.(less than 60 minutes)

SYMBOLS



Batch Code



Consult Instructions for use



Manufacturer



Authorised Representative in the European Community



Keep Dry



Caution



Sterilized Using Steam or Dry heat

WARRANTY AND LIMITATION OF LIABILITY

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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