CE 0197

Instructions for use
Please read carefully and retain for future reference.

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NiTi-Endo-File

1. Indication
System containing rotary files made of NiTi for the mechanical preparation of root canals, according to the Crown-Down technique.

2. Contra-indication
Use in root canals with pronounced abrupt curves in the apical region and severely calcified root canals

3. Clinical sequence/appropriate use
General information
- Make sure to observe the recommendations for the use of mechanical NiTi instruments and for the cleaning and disinfection of root canals.
- To be used in lubricated canals only (it is recommended to use a lubricant containing EDTA)
- Clean the instruments periodically during the treatment by means of mechanical procedures. Rinse canal thoroughly to ensure efficient removal of debris. Ensure patency of the canal by means of suitable manual instruments, to reduce the risk of blockage of the canal during the preparation.

Prior to the use of NiTi-Endo-Files
- Determine the morphology of the canal by means of diagnostic radiographs
- Prepare a straight canal access, for example with Gates burs
- Ensure patency of the canal by means of suitable manual instruments up to ISO size 015, for example with a K-file.

Appropriate use of the NiTi-Endo-Files
- The instruments are used in “picking motion”, i. e. the files are used gently up and down the canal wall during a period of max. 5 - 8 seconds, according to the Crown-Down principle.
- Use in a torque-limited contra-angle at an optimal speed of 250 rpm. The maximum permissible speed is 500 rpm. Make sure not to exceed the following maximum torques:
- 0,8 Ncm for instruments of size 015 - 030
- 1,4 Ncm for instruments exceeding size 035

Instrument sequence:
Narrow canals: DV04 in size 025/DV04 in size 020/DV04 in size 015
Medium canals: DV04 in size 035/DV04 in size 030/DV04 in size 025
Wide canals: DV04 in size 045/DV04 in size 040/DV04 in size 035
- Clean the instruments periodically during the treatment by means of mechanical procedures. Rinse the root canal thoroughly to ensure efficient removal of debris. Check instruments for plastic deformations and discard any imperfect files.
- Monitor and record carefully how many times each instrument has been used (3 - 5 canals at most, when used in extremely curved canals, discard after one use, in order to avoid fracture of the instrument due to material fatigue).

4. Further treatment
After the administration of a medicament, if necessary, the root canal can be filled according to the usual methods, for example with condensed gutta-percha, a carrier based filling system or a thermo plastic procedure.

5. Recommendations for maintenance
All NiTi-Endo-Files are supplied in non-sterile condition. They therefore have to be cleaned, disinfected and sterilised prior to each use. Remove silicone stopper from the file prior to reprocessing. Disinfect the files with a mildly alkaline disinfecting and cleaning agent for rotary instruments. For recommendations for use (immersion time, concentration, suitability) of the disinfecting and cleaning agents please refer to the instructions provided by the manufacturer of the agents used. The instruments can be reprocessed in the thermo disinfector, provided that the agent used is suitable for rotary instruments. Disinfecting and cleaning agents must be rinsed off thoroughly with water and the instruments must be dried carefully (preferably with compressed air according to the recommendations of the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute). Do not store the instruments for a longer period in wet or humid condition. Ensure that all traces of Na0Cl are removed and limit contact to just a few minutes. The instruments must not come in contact with each other during the cleaning in the ultrasonic bath. Carry out a visual check of the instruments. Damaged or blunt instruments must be rejected and their use discontinued. The operator of medical products is responsible for seeing that proper treatment is carried out by qualified personnel, using the appropriate materials and suited equipment, as recommended by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute. Work instruction with regard to proper reprocessing of instruments according to DIN EN ISO 17664 can be downloaded from our web site www.drendel.com or requested from the manufacturer Drendel + Zweiling. Sterilization is carried out in the autoclave at 134°C. The recommendations provided by the manufacturer of the device have to be observed.

6. Safety and liability
- Please also refer to the recommendations for use and safety instructions in the current D+Z catalogue.
- It is the responsibility of the user to check the products prior to use as to whether they suited for the intended purpose.
- The user is responsible for the correct use of the instruments.
- In case of contributory negligence by the user, D+Z partly or totally declines liability for all resulting damages, particularly due to non-observance of our instructions for use as well as misuse by the user.