Hand Held Endodontic Instruments

Instructions for Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by dental professionals only.
SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Perfection Plus Hand Held Endodontic Instruments are manufactured from stainless steel and are supplied in a non-sterile state. All instruments intended for root preparation manufactured in accordance with the specifications of the current ISO 3630 are intended to be used by dental professionals during the root canal treatment phases. Easy identification of products with a triple coding system, according to the current ISO 3630standard: colour coded, symbol and number. All manual instruments have a safety hole in the handle (parachute hole).

Product Name	Hand Held Endodontic Instruments
Company Name	Perfection Plus Ltd
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PRODUCT CODE – REF

004/1000 – 004/1016 Hand K File 21mm Pk 6
004/1020 – 004/1036 Hand K File 25mm Pk 6
004/1040 – 004/1056 Hand K File 28mm Pk 6
004/1060 – 004/1076 Hand K File 31mm Pk 6
004/1100 – 004/1116 Hand Reamer 21mm Pk 6
004/1120 – 004/1136 Hand Reamer 25mm Pk 6
004/1140 – 004/1156 Hand Reamer 28mm Pk 6
004/1201 – 004/1216 Hedstrom Files 21mm Pk 6
004/1221 – 004/1236 Hedstrom Files 25mm Pk 6
004/1241 – 004/1256 Hedstrom Files 28mm Pk 6
004/1262 – 004/1276 Hedstrom Files 31mm Pk 6
004/1600 – 004/1629 Barbed Broaches 21mm Pk 6
004/1600 – 004/1629 Barbed Broaches 21mm Pk 6
004/1820 – 004/1832 Pluggers 25mm Pk 6
004/1840 – 004/1846 Spreaders 21mm Pk 6
004/1850 – 004/1856 Spreaders 25mm Pk 6

INDICATIONS FOR USE
Hand K Files, Hand Reamers, Hedstrom, Barbed Broaches and Spreaders are instruments used for cleaning, disinfecting and shaping dental root canals in a single patient during a single procedure.

WARNINGS/CONTRAINDICATIONS
1. Strict Medical Contra-indication : heart disease at high risk of infection endocarditis if the pulp is neocrotic.
2. Relative medical- contra-indication: Cardiopathy at high risk of infective endocarditis if the tooth is live and cardiopathy at lower risk in all cases.
3. Root instruments with a stainless steel or titanium nickel blade should not be used in cases of known allergic sensitivity or the patient.
4. Tooth without functional future, which cannot be repaired in a sustainable way.
5. Tooth with insufficient periodontal support.

STORAGE (pre-use): Store in a dry clean environment at ambient temperature.

CLINCAL PRECAUTIONS AND WARNINGS

1. These instruments are intended for use in hospitals, clinics and dental practices.
2. Endodontic care should only be performed if three conditions are met: sealed operating area (dental dam); endodontic area is fully accessible, it is performed in one session.
3. Ensure sterilisation of products before first use and before reuse.

4. Multiple uses and sterilisations can deform the blade and tus weaken it. Using a weakened instrument can lead to accidental breakage.

BEFORE USE

1. The products are supplied non-sterile. It is essential to follow the steps of cleaning, disinfecting and sterilising before first use or reuse in accordance with current ISO 17664 standard.
2. Remove damaged or poorly performing products
3. The responsibility for the sterilisation of products prior to first use and reuse lies with the user
4. For your safety, we recommend the use of PPE (Personal Protective Equipment), for example gloves and eye protection.
5. Only use disinfectants with proven efficiency (EU Labelling, FDA approved) including the one in our current sterilisation cleaning protocol and follow it.
6. Clean disinfect, rinse, and dry devices with a washer-disinfector. (Ensure compliance according to the current EN ISO 15833-1 standard and follow the manufacturers instruction manual).
7. After drying, place the devices in pouches for sterilisation. (Ensure compliance with the current EN ISO 11607-1 standard).
8. Sterilise according to the prion program (134°C for 180 minutes) in an autoclave. (Ensure compliance according to the current standard EN 13060+A1 and follow the manufacturers instruction manual).
9. When sterilising multiple devices during a single autoclave cycle, be sure not to exceed its maximum load. Avoid sterilising devices of different material in the same load.

USAGE

1. It is essential to follow the cleaning, disinfecting and sterilising stages before first use or reuse (see our recommendations in our current sterilisation cleaning protocol).
2. Study x-ray images from different angles to determine the width length and curvature of the root canal.
3. Depending on the intended use, select the most appropriate endodontic instruments (type and ISO coding) for shaping, widening, cleaning and filling dental root canals.
4. Before using the instruments, make sure there is no damage, deformation, rust and scratches. Irrigate with a solution of sodium hypochlorite (2.5%) and introduce the endodontic instruments by applying vertical and back and forth movements in the root canal. Perform the final rinse with EDTA solution and then with hypochlorite and dry.
5. The rigidity of endodontic manual steel allows you to deal with blockages and calcifications.
6. Use these products carefully, to avoid needle stick injury.

STORAGE AND DISPOSAL

Keep sterilised devices in a cool, clean, dry place. Used instruments must be disposed of in accordance with current regulations, following a protocol for cross-infection control.

CAUTION

Should a serious incident in relation to the product occur, it should be reported to the manufacturer and the competent authority.

BATCH CODE/EXPIRY

The batch code is shown as LOT. Please quote this in all correspondence.
The product lifetime is estimated to be 3 years from the date of manufacture but may vary depending on the method of use (cutting, conditions), the frequency of use, or when the sterilisation has reached a maximum of 10 cycles.

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