

Eco+ 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 DESIGNED FOR USE IN DENTISTRY

IDENTIFICATION

Perfection Plus Eco+ Hand-Held Endodontic instruments have an operating tip and shank made stainless steel including nickel and chromium. The instruments are supplied non-sterile and should be sterilised before use. 

Product Name	Eco+ Barbed Broaches Eco+ Spreaders Eco+ Pluggers	Eco+ Hedstrom Files Eco+ Hand Reamers Eco+ Hand K Files
Company Name	 Perfection Plus Ltd	
Company Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK	
Company Phone No.	+44 (0) 2380 866 677	

PRODUCT CODE –

004/5000	Eco+ Hand K Files 21mm 10 pk 6	004/5825	Eco+ Hand K Files 31mm 25 pk 6	004/5874	Eco+ Pluggers 25mm 35 pk 6
004/5000A	Eco+ Hand K Files 21mm 08 pk 6	004/5826	Eco+ Hand K Files 31mm 30 pk 6	004/5875	Eco+ Pluggers 25mm 40 pk 6
004/5000B	Eco+ Hand K Files 21mm 06 pk 6	004/5827	Eco+ Hand K Files 31mm 35 pk 6	004/5876	Eco+ Pluggers 25mm 15/40 pk 6
004/5001	Eco+ Hand K Files 21mm 15 pk 6	004/5030	Eco+ Hedstrom Files 21mm 10 pk 6	004/5060	Eco+ Hand Reamers 21mm 10 pk 6
004/5002	Eco+ Hand K Files 21mm 20 pk 6	004/5030A	Eco+ Hedstrom Files 21mm 08 pk 6	004/5061	Eco+ Hand Reamers 21mm 15 pk 6
004/5003	Eco+ Hand K Files 21mm 25 pk 6	004/5030B	Eco+ Hedstrom Files 21mm 06 pk 6	004/5062	Eco+ Hand Reamers 21mm 20 pk 6
004/5004	Eco+ Hand K Files 21mm 30 pk 6	004/5031	Eco+ Hedstrom Files 21mm 15 pk 6	004/5063	Eco+ Hand Reamers 21mm 25 pk 6
004/5005	Eco+ Hand K Files 21mm 35 pk 6	004/5032	Eco+ Hedstrom Files 21mm 20 pk 6	004/5064	Eco+ Hand Reamers 21mm 30 pk 6
004/5006	Eco+ Hand K Files 21mm 40 pk 6	004/5033	Eco+ Hedstrom Files 21mm 25 pk 6	004/5065	Eco+ Hand Reamers 21mm 35 pk 6
004/5007	Eco+ Hand K Files 21mm 45 pk 6	004/5034	Eco+ Hedstrom Files 21mm 30 pk 6	004/5066	Eco+ Hand Reamers 21mm 40 pk 6
004/5008	Eco+ Hand K Files 21mm 15/40 pk 6	004/5035	Eco+ Hedstrom Files 21mm 35 pk 6	004/5067	Eco+ Hand Reamers 21mm 45 pk 6
004/5008A	Eco+ Hand K Files 21mm 45/80 pk 6	004/5036	Eco+ Hedstrom Files 21mm 40 pk 6	004/5068	Eco+ Hand Reamers 21mm 50 pk 6
004/5009	Eco+ Hand K Files 21mm 50 pk 6	004/5037	Eco+ Hedstrom Files 21mm 45 pk 6	004/5069	Eco+ Hand Reamers 21mm 55 pk 6
004/5009A	Eco+ Hand K Files 25mm 08 pk 6	004/5038	Eco+ Hedstrom Files 21mm 15/40 pk 6	004/5070	Eco+ Hand Reamers 21mm 60 pk 6
004/5009B	Eco+ Hand K Files 25mm 06 pk 6	004/5039	Eco+ Hedstrom Files 25mm 06 pk 6	004/5071	Eco+ Hand Reamers 21mm 70 pk 6
004/5010	Eco+ Hand K Files 25mm 10 pk 6	004/5040	Eco+ Hedstrom Files 25mm 10 pk 6	004/5072	Eco+ Hand Reamers 21mm 80 pk 6
004/5011	Eco+ Hand K Files 25mm 15 pk 6	004/5040A	Eco+ Hedstrom Files 25mm 08 pk 6	004/5073	Eco+ Hand Reamers 21mm 15/40 pk 6
004/5012	Eco+ Hand K Files 25mm 20 pk 6	004/5041	Eco+ Hedstrom Files 25mm 15 pk 6	004/5074	Eco+ Hand Reamers 21mm 45/80 pk 6
004/5013	Eco+ Hand K Files 25mm 25 pk 6	004/5042	Eco+ Hedstrom Files 25mm 20 pk 6	004/5080	Eco+ Hand Reamers 25mm 10 pk 6
004/5014	Eco+ Hand K Files 25mm 30 pk 6	004/5043	Eco+ Hedstrom Files 25mm 25 pk 6	004/5081	Eco+ Hand Reamers 25mm 15 pk 6
004/5015	Eco+ Hand K Files 25mm 35 pk 6	004/5044	Eco+ Hedstrom Files 25mm 30 pk 6	004/5082	Eco+ Hand Reamers 25mm 20 pk 6
004/5016	Eco+ Hand K Files 25mm 40 pk 6	004/5045	Eco+ Hedstrom Files 25mm 35 pk 6	004/5083	Eco+ Hand Reamers 25mm 25 pk 6
004/5017	Eco+ Hand K Files 25mm 45 pk 6	004/5046	Eco+ Hedstrom Files 25mm 40 pk 6	004/5084	Eco+ Hand Reamers 25mm 30 pk 6
004/5017D	Eco+ Hand K Files 25mm 70 pk 6	004/5047	Eco+ Hedstrom Files 25mm 45 pk 6	004/5085	Eco+ Hand Reamers 25mm 35 pk 6
004/5017E	Eco+ Hand K Files 25mm 80 pk 6	004/5047A	Eco+ Hedstrom Files 25mm 50 pk 6	004/5086	Eco+ Hand Reamers 25mm 40 pk 6
004/5018	Eco+ Hand K Files 25mm 15/40 pk 6	004/5048	Eco+ Hedstrom Files 25mm 15/40 pk 6	004/5087	Eco+ Hand Reamers 25mm 45 pk 6
004/5018A	Eco+ Hand K Files 25mm 45/80 pk 6	004/5049	Eco+ Hedstrom Files 25mm 45/80 pk 6	004/5088	Eco+ Hand Reamers 25mm 50 pk 6
004/5019	Eco+ Hand K Files 25mm 50 pk 6	004/5050	Eco+ Hedstrom Files 28mm 10 pk 6	004/5089	Eco+ Hand Reamers 25mm 55 pk 6
004/5019A	Eco+ Hand K Files 25mm 55 pk 6	004/5050A	Eco+ Hedstrom Files 28mm 08 pk 6	004/5090	Eco+ Hand Reamers 25mm 60 pk 6
004/5019B	Eco+ Hand K Files 25mm 60 pk 6	004/5051	Eco+ Hedstrom Files 28mm 15 pk 6	004/5091	Eco+ Hand Reamers 25mm 70 pk 6
004/5020	Eco+ Hand K Files 28mm 10 pk 6	004/5052	Eco+ Hedstrom Files 28mm 20 pk 6	004/5092	Eco+ Hand Reamers 25mm 80 pk 6
004/5020A	Eco+ Hand K Files 28mm 08 pk 6	004/5053	Eco+ Hedstrom Files 28mm 25 pk 6	004/5093	Eco+ Hand Reamers 25mm 15/40 pk 6
004/5020B	Eco+ Hand K Files 28mm 06 pk 6	004/5054	Eco+ Hedstrom Files 28mm 30 pk 6	004/5094	Eco+ Hand Reamers 25mm 45/80 pk 6
004/5021	Eco+ Hand K Files 28mm 15 pk 6	004/5055	Eco+ Hedstrom Files 28mm 35 pk 6	004/5100	Eco+ Hand Reamers 28mm 10 pk 6

004/5022	Eco+ Hand K Files 28mm 20 pk 6	004/5056	Eco+ Hedstrom Files 28mm 40 pk 6	004/5101	Eco+ Hand Reamers 28mm 15 pk 6
004/5023	Eco+ Hand K Files 28mm 25 pk 6	004/5057	Eco+ Hedstrom Files 28mm 45 pk 6	004/5102	Eco+ Hand Reamers 28mm 20 pk 6
004/5024	Eco+ Hand K Files 28mm 30 pk 6	004/5058	Eco+ Hedstrom Files 28mm 15/40 pk 6	004/5103	Eco+ Hand Reamers 28mm 25 pk 6
004/5025	Eco+ Hand K Files 28mm 35 pk 6	004/5831	Eco+ Hedstrom Files 31mm 06 pk 6	004/5104	Eco+ Hand Reamers 28mm 30 pk 6
004/5026	Eco+ Hand K Files 28mm 40 pk 6	004/5840	Eco+ Hedstrom Files 31mm 15/40 pk 6	004/5105	Eco+ Hand Reamers 28mm 35 pk 6
004/5027	Eco+ Hand K Files 28mm 45 pk 6	004/5841	Eco+ Hedstrom Files 31mm 45/80 pk 6	004/5106	Eco+ Hand Reamers 28mm 40 pk 6
004/5028	Eco+ Hand K Files 28mm 50 pk 6	004/5880	Eco+ Barbed Broaches 21mm ISO 20 Yellow pk 10	004/5113	Eco+ Hand Reamers 28mm 15/40 pk 6
004/5028A	Eco+ Hand K Files 28mm 60 pk 6	004/5881	Eco+ Barbed Broaches 21mm ISO 25 Red pk 10	004/5114	Eco+ Hand Reamers 28mm 45/80 pk 6
004/5028B	Eco+ Hand K Files 28mm 70 pk 6	004/5882	Eco+ Barbed Broaches 21mm ISO 30 Blue pk 10	004/5850	Eco+ Spreader 21mm 15 pk 6
004/5028C	Eco+ Hand K Files 28mm 80 pk 6	004/5883	Eco+ Barbed Broaches 21mm ISO 35 Green pk 10	004/5851	Eco+ Spreader 21mm 20 pk 6
004/5029	Eco+ Hand K Files 28mm 15/40 pk 6	004/5884	Eco+ Barbed Broaches 21mm ISO 40 Black pk 10	004/5852	Eco+ Spreader 21mm 25 pk 6
004/5828	Eco+ Hand K Files 31mm 40 pk 6	004/5885	Eco+ Barbed Broaches 21mm ISO 10/40 pk 10	004/5853	Eco+ Spreader 21mm 30 pk 6
004/5829	Eco+ Hand K Files 31mm 15/40 pk 6	004/5886	Eco+ Barbed Broaches 25mm ISO 20 Yellow pk 10	004/5854	Eco+ Spreader 21mm 35 pk 6
004/5830	Eco+ Hand K Files 31mm 45/80 pk 6	004/5887	Eco+ Barbed Broaches 25mm ISO 25 Red pk 10	004/5855	Eco+ Spreader 21mm 40 pk 6
004/5029A	Eco+ Hand K Files 28mm 45/80 pk 6	004/5888	Eco+ Barbed Broaches 25mm ISO 30 Blue pk 10	004/5856	Eco+ Spreader 21mm 15/40 pk 6
004/5702	Eco+ Hand K Reamers 21mm 80 Pk 6	004/5889	Eco+ Barbed Broaches 25mm ISO 35 Green pk 10	004/5857	Eco+ Spreader 25mm 15 pk 6
004/5805	Eco+ Hand K Reamers 25mm 35 Pk 6	004/5890	Eco+ Barbed Broaches 25mm ISO 40 Black pk 10	004/5858	Eco+ Spreader 25mm 20 pk 6
004/5820	Eco+ Hand K Files 31mm 06 pk 6	004/5891	Eco+ Barbed Broaches 25mm ISO 10/40 pk 10	004/5859	Eco+ Spreader 25mm 25 pk 6
004/5821	Eco+ Hand K Files 31mm 08 pk 6	004/5870	Eco+ Pluggers 25mm 15 pk 6	004/5860	Eco+ Spreader 25mm 30 pk 6
004/5822	Eco+ Hand K Files 31mm 10 pk 6	004/5871	Eco+ Pluggers 25mm 20 pk 6	004/5861	Eco+ Spreader 25mm 35 pk 6
004/5823	Eco+ Hand K Files 31mm 15 pk 6	004/5872	Eco+ Pluggers 25mm 25 pk 6	004/5862	Eco+ Spreader 25mm 40 pk 6
004/5824	Eco+ Hand K Files 31mm 20 pk 6	004/5873	Eco+ Pluggers 25mm 30 pk 6	004/5863	Eco+ Spreader 25mm 15/40 pk 6

INDICATIONS FOR USE

The product are used in the treatment of endodontic diseases.

- Eco+ Hand K Files are used to clean and shape the root canal walls.
- Eco+ Hedstrom Files are cutting instruments used to enlarge the root canal
- Eco+ Reamers are cutting instruments used to smooth the root canal walls.
- Eco+ Pluggers and Eco+ Spreaders are smooth conical shaped instruments a with a flat tip. They are used vertically to condense gutta percha and other filling materials.
- Eco+ Barbed Broaches are designed for the fast removal of pulp tissue to enlarge the canal.

INTENDED USE

Medical devices used to explore, shape, clean and/or assist in filling the root canal system during dental treatment. This product is suitable for use in hospitals, clinics and by qualified dentists.

EXPECTED USERS

Endodontic instruments can only be used in a clinical or hospital setting, following good dental practice, by qualified dental professionals such as general practitioners, as well as root canal specialists (endodontists).

SPECIFICATIONS

Under the provisions of ISO 3630 performance test, product durability for twisting and bending must exceed specified value of our standard.

CONTRAINDICATIONS

Do not use on patients with a nickel allergy.

STRUCTURAL COMPOSITION, COMPOSITION AND COMPATIBLE EQUIPMENT

It is made of 304 stainless steel and consists of an operating part, a silicone stopper and a PBT handle. They are reusable devices, supplied in a non-sterile state.

WARNING

Follow the Cleaning and Maintenance instructions strictly to minimise the following risks to the device, patient and/or the user:

- Instrument breakage
- Cross-contamination
- Heat generation due to insufficient lubrication and irrigation
- Swallowing of working part of the instruments
- Toxic or allergic reactions caused by processing residues.

PREVENTATIVE MEASURES

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- For your own safety, wear personal protective equipment (glasses, gloves, mask).

- Inspect the packaging before use and do not use the instruments if the packaging is damaged.
- Check the instruments before use for signs of defect such as deformation (bent or unwound) breakage, corrosion, damaged cutting edges, loss of colour coding or marking. With these indications the devices are not able to fulfil the intended use with the required safety level and instruments should be discarded.
- Check instruments and clean the working part frequently during instrumentation, inspecting for signs of distortion elongation or wear, such as uneven flutes, dull spots. With these indications the devices are not able to fulfil the intended use with the required safety level and instruments should be discarded.
- Instruments should not be fully immersed in a sodium hypochlorite solution (NaOCl). Only the working part of the instrument, which is in contact with the patient should be immersed in an NaOCl solution concentrate of NOT more than 5%.
- Exercise caution in the apical area and in canals that divide, and /or exhibit abrupt curvatures or re-curvatures.
- Irrigate abundantly and frequently the canal throughout the procedure and after each instrument used (according to good dental practice).
- Always use minimal apical pressure. Never force the file down the canal.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:
 - Use a new file and discard after the canal has been treated (single canal use).
 - Use manual instead of rotary files
 - Use small size, flexible or/and NiTi files (this will help avoid canal transportation).
 - Visually inspect the working part for all the defects listed in the former paragraph during use (i.e. after each wave).
 - Avoid the standard reaming continual-rotational motion and instead use small angle motions (filling motion, watch-winding oscillation-motion, or balanced-force technique) in order to limit the rotational bending fatigue on the instrument and improve their expected life.

ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

STORAGE CONDITIONS

Keep products in a dry, clean environment away from moisture and direct sunlight.

STEP BY STEP INSTRUCTIONS

1. Sterilisation and disinfection (Cleaning and Maintenance)
2. Use of rubber dam or other suitable isolation techniques is recommended
3. Preliminary confirmation of working length based on judgement of radiology image.
4. **Eco+ Spreaders and Pluggers** - Use an appropriate size file and manually rotate in a reciprocating manner close to 45° to clear or compress the filling material in the root canal.
5. **Eco+ Barbed Broaches** - Use an appropriate size file, dip in the paste, rotate gently and enter the 2/3 position of the root canal channel, repeat 1-2 times. Use slow movements to avoid the formation of bubbles.
6. **Eco+ K Files, Reamers and Hedstrom Files** In the environment of sodium hypochlorite solution, use a suitable file to advance with a slight thrust of 2-3mm, reaching the working length on or more times.
7. Use only gentle force at all times.
8. Selection of a suitable paste delivery device according to the width and length of the root canal.
9. The use of viscose chelating agents can reduce the release of metal ions from the instrument.
10. Do not use this instrument for the purposes other than dental oral applications.
11. The cleaning agent solution should comply with the treatment medication standards. Do not use concentrated cleaning agents as they will damage the surface of the instrument.
12. Products shall be disposed of in accordance with local regulations for the safe disposal of contaminated sharp devices.

CLEANING AND MAINTENANCE

- The product is non-aseptic and needs to be cleaned, disinfected and sterilised before use. Thorough cleaning and disinfection is a prerequisite for effective sterilisation. The operator must follow the manufacturers operating instructions.
- It is recommended that the instrument is cleaned and disinfected by mechanical means.
- High temperature disinfection (disinfector/CDU) always ensure that the disinfector is certified by an authority (e.g. VAH/DGHM FDA or CE label according to DIN EN ISO 15883).
- High temperature disinfection (93°C for at least 10 minutes or Ao value > 3000) can be performed (chemical risk due to residue on the instrument).
- The operator is responsible for using proper instrument disinfection procedures, adequate cleaning cycles, using only sterile or low bacterial content (10 cfu/ml) and endotoxin-free water (0.25 eu-/ml such as high purity water HPW), and regular maintenance of the sterilized instrument.
- When choosing cleaning agents, make sure that they are appropriate for cleaning instruments. If it is known that high-temperature disinfection is not possible, sanitizers that are certified by an authority (such as VAH/DGHM or FDA certificate or CE label) and are compatible with cleaning agents should be selected used as per the manufacturer's instructions. must comply with the concentration ratios indicated by the detergent, sanitizer manufacturer.

Mechanical cleaning and disinfection procedures:

- Select the appropriate module for pre-clean and place the instrument in a sterilisation pouch. Instruments should always be placed in a container and not loose.

- Put the sterilisation pouch into the steriliser in a rack and start the program.
- At the end of the program, remove the sterilization pouch from the steriliser.
- After the removal dry if necessary and check the sterilisation pouch for any damages. Store the instrument in a clean place.
- Place in a sterilisation pouch only with like instruments. Do not overfill the pouch. Please take care not to let the instruments touch each other.

Manual cleaning and disinfection procedures

Cleaning

- Place the instrument in a sterilisation basket and place in the cleaning sink/tank for the specified contact time. The instrument should be fully submersed.
- The sterilisation basket should be removed from the solution and rinsed with clean water for at least 3 minutes.

Disinfection

- The sterilising box containing the cleaning and inspection apparatus shall be put into the sterilising trough within the specified contact time.
- Remove the instrument form the tank and rinse thoroughly with water for 5 minutes.
- Inspect, dry and package the instrument as soon as possible after the removal.
- If possible, remove instruments and products that cannot be cleaned directly in the steriliser box and place them in the steriliser. Please take care not to let the instruments touch each other.

Sterilize the product using a high-pressure steam steriliser in accordance with the prescribed methods and terminology. No other sterilisation methods shall be used.

High pressure steam sterilisation method:

1. Vacuum fraction (at least 3 cycles) or gravimetric method 1 (product must be fully dried).
2. Steam sterilisers that meet the requirements of DIN EN 13060 or DIN EN 285.
3. In accordance with the provisions of ISO 17665-1 certification (effective installation, Operation Qualification and product performance qualification).
4. Effective sterilisation is achieved at 121°C for at least 20 minutes of 134°C for at least 5 minutes, as specified in ISO 17665-1. If local regulations have higher requirements, then 134°C for 18 minutes (to eliminate potential prions) can be used.
5. Put the product in a sterilisation pouch and place it on a sterilisation rack, or bur stand, for sterilisation autoclave cycles with reference to the following terms.
6. Rapid sterilisation or the use of sterilisation methods for unpackaged instruments shall NOT be allowed. Do NOT use hot air sterilisation, radiation sterilisation, formaldehyde or oxirane and ion sterilisation.
7. Do not use high pressure steam steriliser that heats to more than 200°C including the drying process.
8. Regarding use of medical cleaning agent, follow the manufacturers instruction manual strictly.
9. Check all instruments after cleaning or cleaning/disinfection. Any defective instruments should be discarded immediately. Defects include: plastic deformation, instrument bending, thread grinding, cutting surface damage, blunt cutting tool, missing size label, corrosion.

OTHER INFORMATION

Any serious incident in relation to the product should be reported to the manufacturer and the Competent Authority according to local regulations.

CAUTION



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

LOT NUMBER

The batch code is shown as LOT. Please quote this in all correspondence.

EXPLANATION OF SYMBOLS USED

	Reference Number		Caution - For Dental Use only
	Do not use if packaging is damaged.		Expiry Date
	Silicone		Lot number
	Autoclave temperature		Importer
	Keep dry		Manufacturer
	Medical Device		EC Representative
	Stainless Steel		

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