

# **EndoPLUS Alternate Path File/ EndoPLUS Alternate File**

## **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 EndoPLUS Alternate Path File and EndoPLUS Alternate File have an operating tip made from Niti material with a brass shank, the operating tip has a cutting edge. The limit block is made of silicone. The instruments are supplied non-sterile and should be sterilised before use.



| Product Name      | EndoPLUS Alternate File Pk4 and EndoPLUS Alternate Path File Pk 4 |
|-------------------|---|
| 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 - REF

#### **Alternate Path File - Cross Section**



| 004/6050 | Alternate Path File 21mm ISO 15 Pk 4 | 004/6052 | Alternate Path File 31mm ISO 15 Pk 4 |
|----------|--------------------------------------|----------|--------------------------------------|
| 004/6051 | Alternate Path File 25mm ISO 15 Pk 4 |          |                                      |

#### Alternate File – Cross Section



| Aiternate i | Tile - Cross Section                        |          |   |
|-------------|---|----------|---|
| 004/6020    | Alternate File 21mm ISO 20 Yellow Pk 4      | 004/6033 | Alternate File 25mm ISO 45 White Pk 4       |
| 004/6021    | Alternate File 21mm ISO 25 Red Pk 4         | 004/6034 | Alternate File 25mm ISO 20-45 Assorted Pk 4 |
| 004/6022    | Alternate File 21mm ISO 35 Green Pk 4       | 004/6040 | Alternate File 31mm ISO 20 Yellow Pk 4      |
| 004/6023    | Alternate File 21mm ISO 45 White Pk 4       | 004/6041 | Alternate File 31mm ISO 25 Red Pk 4         |
| 004/6024    | Alternate File 21mm ISO 20-45 Assorted Pk 4 | 004/6042 | Alternate File 31mm ISO 35 Green Pk 4       |
| 004/6030    | Alternate File 25mm ISO 20 Yellow Pk 4      | 004/6043 | Alternate File 31mm ISO 45 White Pk 4       |
| 004/6031    | Alternate File 25mm ISO 25 Red Pk 4         | 004/6044 | Alternate File 31mm ISO 20-45 Assorted Pk 4 |
| 004/6032    | Alternate File 25mm ISO 35 Green Pk 4       |          |   |

| Model                         | ISO Size | Taper | Length          | Torque      | Speed  |
|-------------------------------|----------|-------|-----------------|-------------|--------|
| EndoPLUS Alternate Files      | #20      | 07    |                 | 2.0-3.0N/cm | 350rpm |
|                               | #25      | 07    | 21, 25, 31mm    | 2.0-3.0N/cm | 350rpm |
|                               | #35      | 06    | 21, 25, 5111111 | 2.0-3.0N/cm | 350rpm |
|                               | #45      | 05    |                 | 2.0-3.0N/cm | 350rpm |
| EndoPLUS Alternate Path Files | #15      | 02    | 21, 25, 31mm    | 5.0N/cm     | 300rpm |

## **INDICATIONS FOR USE**

The EndoPLUS Alternate Files are for use during an endodontic treatment in a case of root canal infection, for shaping and cleaning the root canal system. They should be used in conjunction with the matching motor and should be sterilised before use.

## **CONTRAINDICATIONS AND PROHIBITIONS**

Do not use on patients with a nickel allergy.

#### **PRECAUTIONS FOR USE**

1. This product is provided non-sterile and must be sterilised before use. For the sterilisation method see Disinfection, Sterilisation and Cleaning.





- 2. These are single use instruments.
- 3. This product needs to be used in conjunction with a suitable motor for reciprocating motion.
- 4. This product is not suitable for the preparation of complex root canals with acute angles.

- 5. Do not use glutaraldehyde or other disinfectants.
- 6. Once used, dispose of this product in accordance with local laws.

### **TECHNIQUE**

Select a suitable Endodontic Motor:

## **EndoPLUS Alternate Path File**

- 1. Prepare straight line access to canal orifice.
- 2. Establish glide path using chelating agent and a K File ISO 10.
- 3. Determine working length with X Ray and/or Apex Locator and choose the appropriate length of EndoPLUS Alternate Path File 0.15mm.
- 4. Irrigate and then with gentle pressure let the file passively progress until the working length is reached.
- 5. Irrigate the expanded glide path and reconfirm working length before shaping.

#### **EndoPLUS Alternate File**

- 1. Initiate the shaping procedure using Sodium hypochlorite and a Primary Endo Plus Alternate File ISO 25/.07.
- 2. With gentle pressure let the file progress to pre-enlarge the coronal two thirds of the canal.
- 3. Gently continue until the working length is reached.
- 4. Remove the file and ensure canal is adequately irrigated.
- 5. Inspect the file, if the cutting-edge grooves are loaded with dentinal debris the shape is completed.
- 6. If the file doesn't progress use the EndoPLUS Alternate File ISO 20/.07 in one or more passes to working length and then use the Primary file to optimize shape.
- 7. If the Primary file is loose or contains no dentinal debris select the EndoPLUS Alternate Medium ISO 35/0.6 or EndoPLUS Alternate Large File 45/.05 to continue shaping the canal.

# **DISINFECTION, STERILISATION AND CLEANING**

Autoclave at 134°C, relative pressure 202.8KPa, for not less than 3 minutes.



## **STORAGE**

Store at room temperature.

## **PACKAGING**

Minimum packing unit: 4 pcs. Assorted packs contain 1 of each size, ISO 20-45.

## **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**

|               | For use with a Right Angle hand piece                    |             | Distributor                         |
|---------------|--|-------------|-------------------------------------|
| REF           | Reference Number   | $\triangle$ | Caution - For Dental Use only       |
| NITI          | Nickel Titanium  | $\subseteq$ | Expiry Date                         |
| Sil           | Silicone   | LOT         | Lot number                          |
| 134 °C<br>111 | Autoclave temperature                                    |             | Importer                            |
| 2             | Single Use only  | ***         | Manufacturer                        |
| MD            | Medical Device   | EC REP      | EC Representative                   |
| Reciprocating | For use with a specialist Reciprocating motion handpiece | <b>®</b>    | Do not use if packaging is damaged. |



Perfection Plus Ltd 6 Westwood Court Brunel Road, Totton Hampshire SO40 3WX, UK www.perfectionplus.com Sungo Europe B.V.
Olympisch Stadion
24, 1076DE,
Amsterdam,
Netherlands



Perfection Plus EU Ltd The Black Church St Mary's Place. Dublin, Ireland, DO7 P4AX Regulatory@perfectionplus.com

