## Prophy+ Cups and Brushes

### Instructions for Use

**IMPORTANT**

Read this 'Instructions for Use' document before handling. This product is for professional use only.

**IDENTIFICATION**

| | |
|---|---|
| Product Name | Prophy+ |
| 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

| | |
|---|---|
| PP005/0007 | Prophy+ Brushes Bristle RA pk 100 |
| PP005/0008 | Prophy+ Brushes Bristle RA pk 144 |
| PP005/3004 | Prophy+ Brushes Bristle RA pk 150 |
| PP005/5430 | Prophy+ Brushes Bristle RA pk 50 |
| PP005/0060 | Prophy+ Brushes Bristle RA pk 720 |
| PP005/0031 | Prophy+ Brushes Bristle Screw In pk 100 |
| PP005/3003 | Prophy+ Brushes Bristle Screw In pk 150 |
| PP005/5431 | Prophy+ Brushes Bristle Screw In pk 50 |
| PP005/1002 | Prophy+ Brushes Nylon RA Blue Hard pk 50 |
| PP005/1000 | Prophy+ Brushes Nylon RA Pink Soft pk 50 |
| PP005/0004 | Prophy+ Brushes Nylon RA pk 100 |
| PP005/0006 | Prophy+ Brushes Nylon RA pk 144 |
| PP005/3005 | Prophy+ Brushes Nylon RA pk 150 |
| PP005/0016 | Prophy+ Brushes Nylon RA pk 36 |
| PP005/5435 | Prophy+ Brushes Nylon RA pk 50 |
| PP005/0065 | Prophy+ Brushes Nylon RA pk 720 |
| PP005/1001 | Prophy+ Brushes Nylon RA Purple Medium pk 50 |
| PP005/2003 | Prophy+ Brushes Nylon Screw In Blue Hard pk 50 |
| PP005/2001 | Prophy+ Brushes Nylon Screw In Pink Soft pk 50 |
| PP005/0030 | Prophy+ Brushes Nylon Screw In pk 100 |
| PP005/3006 | Prophy+ Brushes Nylon Screw In pk 150 |
| PP005/2002 | Prophy+ Brushes Nylon Screw In Purple Medium pk 50 |
| PP005/5503 | Prophy+ Latex Free Cups RA Blue Hard pk 50 |
| PP005/6003 | Prophy+ Latex Free Cups RA Blue Hard pk 720 |
| PP005/5501 | Prophy+ Latex Free Cups RA Pink Soft pk 50 |
| PP005/6001 | Prophy+ Latex Free Cups RA Pink Soft pk 720 |
| PP005/5502 | Prophy+ Latex Free Cups RA Purple Medium pk 50 |
| PP005/6002 | Prophy+ Latex Free Cups RA Purple Medium pk 720 |
| PP005/5603 | Prophy+ Latex Free Cups Screw In Blue Hard pk 50 |
| PP005/6103 | Prophy+ Latex Free Cups Screw In Blue Hard pk 720 |
| PP005/5601 | Prophy+ Latex Free Cups Screw In Pink Soft pk 50 |
| PP005/6101 | Prophy+ Latex Free Cups Screw In Pink Soft pk 720 |
| PP005/5602 | Prophy+ Latex Free Cups Screw In Purple Medium pk 50 |
| PP005/6102 | Prophy+ Latex Free Cups Screw In Purple Medium pk 720 |
| PP005/5703 | Prophy+ Latex Free Cups Snap On Blue Hard pk 50 |
| PP005/6203 | Prophy+ Latex Free Cups Snap On Blue Hard pk 720 |
| PP005/5701 | Prophy+ Latex Free Cups Snap On Pink Soft pk 50 |
| PP005/6201 | Prophy+ Latex Free Cups Snap On Pink Soft pk 720 |
| PP005/5702 | Prophy+ Latex Free Cups Snap On Purple Medium pk 50 |
| PP005/6202 | Prophy+ Latex Free Cups Snap On Purple Medium pk 720 |
| PP005/0010 | Prophy+ Polishing Cups RA pk 100 |
| PP005/0009 | Prophy+ Polishing Cups RA pk 144 |
| PP005/3002 | Prophy+ Polishing Cups RA pk 150 |
| PP005/0013 | Prophy+ Polishing Cups RA pk 50 |
| PP005/0039 | Prophy+ Polishing Cups RA pk 720 |
| PP005/0033 | Prophy+ Polishing Cups Screw In pk 100 |
| PP005/0002 | Prophy+ Polishing Cups Screw In pk 144 |
| PP005/3000 | Prophy+ Polishing Cups Screw In pk 150 |
| PP005/5433 | Prophy+ Polishing Cups Screw In pk 50 |
| PP005/0037 | Prophy+ Polishing Cups Screw In pk 720 |
| PP005/0032 | Prophy+ Polishing Cups Snap On pk 100 |
| PP005/0001 | Prophy+ Polishing Cups Snap On pk 144 |
| PP005/3001 | Prophy+ Polishing Cups Snap On pk 150 |
| PP005/5434 | Prophy+ Polishing Cups Snap On pk 50 |
| PP005/0038 | Prophy+ Polishing Cups Snap On pk 720 |

**INTENDED USE**

The devices are indicated for use by qualified dental professionals for a wide range of procedures, including the cleaning and polishing of natural teeth, gold and amalgam fillings, composites, compomers and glass ionomer cements for removing plaque and stains.

**INSTRUCTIONS FOR USE**

The Class 2a medical devices are for use in the mouth only by (or under the instruction of) a qualified dental professional and are manufactured in accordance with the standard ISO 1797, and should only be used in conjunction with a rotary hand piece that conforms to ISO 14457. The operator should ensure that the rotary instrument is correctly installed in the hand piece prior to commencement of any procedure.

The validation of the recommended sterilisation process has been performed by The University of Liverpool, Clinical Dental Sciences Department, UK, L69 3BX reference – Issue No. 1278 dated December 2003. This study and report were initiated and authorised by the British Dental Trade Association (BDIA).

**STERILISATION**

The devices are intended as single use devices, and the instructions therefore apply before first use only. The devices are dental rotary instruments and are supplied mechanically clean but are not sterile and, therefore, should be sterilised before use. Perfection Plus brushes or polishers are proven to function with appropriate mandrels correctly by historical use with no adverse reports.

**CONTAINMENT AT THE POINT OF USE**

Unless there is specific infection or cross-contamination risks, there are no special requirements for containment. The instruments can be transported wet or dry and should be protected from damage to the working part. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in corrosion and should be avoided.

Delay in processing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.

**PREPARATION FOR CLEANING**

There are no special requirements unless infection controls require the use of a disinfectant, in which case a disinfectant agent validated for processing of dental rotary instruments must be used and the disinfectant manufacturers' instructions must be followed.

**CLEANING**

Auto cleaning is the preferred method and should use only validated washer disinfectors and appropriate agents validated for use on the instruments with the selected machine. Follow the washer disinfector and the cleaning agent manufacturers' instructions.

**DRYING**

Dry the instruments using paper towelling.

**INSPECTION**

Inspect the instruments, with the aid of magnification if necessary, and discard any damaged or corroded instruments.

**PACKAGING FOR STERILISATION**


If using a **vacuum** autoclave pack the instruments in dedicated instrument trays or pouches validated for sterilisation.

If using a **non-vacuum** autoclave, the instruments should not be packed or wrapped but be contained in dedicated stands with perforated lids.

NOTE: National legislation may require that the instruments be wrapped in pouches for processing in either type of autoclave.

**STERILISATION**


Autoclave the instruments for a holding time of not less than three minutes at a temperature of 134ºC.

The holding time is the minimum time for which the minimum temperature is sustained. The autoclave manufacturer's instructions must be followed. Care must be taken not to exceed the maximum recommended load for the autoclave.

**STORAGE**

The instruments should be stored in the sterilisation container (stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.

**VALIDATION**

These processes have been validated as being capable of preparing Perfection Plus dental instruments for use. It remains the responsibility of the processor to ensure that the processing as actually performed using the equipment, materials and personnel achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

**PROPER USE:**

- The instruments are for single use only. Do not reuse.
- Inspect the device prior to use for any defects.
- Only use hand piece, angles and turbines that are technically and hygienically flawless, maintained and cleaned.
- Ensure handpieces are maintained in good working order and remain adequately always lubricated to ensure maximum effectiveness of the device. Failure to properly maintain the handpiece can lead to procedural delays, injury to the user or patient, aspiration or swallowing of the device or damage to the preparation site.
- The device and hand piece must be concentric and true running. Instruments that are deformed or no longer run true should not be used and must be disposed of.
- The instruments must be fully inserted into the handpiece and locked where applicable.
- The instruments are to be brought to speed before placing on the object.
- Polish with gentle circular movements.
- Avoid tilting or levering because of the increased risk of breakage.
- Any damaged and incorrectly shaped instruments will cause vibration. Bent or non-concentric instruments must be disposed of.
- Instruments that are deformed or no longer run true should not be used and must be disposed of.
- Wear eye protection.
- Wear a respiratory mask to prevent inhaling any dust and/or debris during the procedure.
- These products must only be used by qualified dental professional.
- Incorrect use produces poor results and increases the risk.
- Incorrect use may harm tissue, cause premature wear, destroy the Instrument, and endanger the operator, patient or third parties.
- The devices are designed and manufactured to perform safely when used in combination with CE marked medical devices (i.e., prophylaxis paste or mandrels if required) which are themselves intended for use in the oral cavity.

(Snap-On devices only)

- To ensure vibration-free working the connected instrument must be centred after mounting on the mandrel or shaft. Any damaged and incorrectly shaped instruments will cause vibration. Bent or non-concentric instruments must be disposed of.
- Snap-On cups are designed for use with a standard mandrel.

**PRESSURE**

Avoid excessive pressing force!

- Excessive pressure must be always avoided.
- Excessive pressure may damage the working sections of rotary polishing instruments or damage the fill material. Heat build-up is also increased.

**RECOMMENDED SPEEDS**

- Maximum Speed 10,0000 rpm
- Keep within the speed range of 1,500- 10,000 rpm
- Never exceed the maximum permitted speed of the product. The recommend speeds and maximum permitted speeds vary from product to product. Always check the recommended speed as stated on the packaging and the corresponding product schedule.
- If you exceed the maximum permitted speed, the instrument tends to vibrate, which may cause damage to the shaft and/or make the instrument break, with a risk to the user, the patient or third parties. Failure to comply with the maximum permitted speed produces an increased safety risk.
- Keep within the speed range of the product being used for the best work results.
- Failure to comply with the permitted maximum speed produces an increased safety risk.

**INTENDED PATIENT GROUPS/INTENDED PURPOSE**

The devices are intended for use on patients of any age. The products are only aimed as a tool for use by the qualified dental professional who is responsible for determining the treatment required by each individual patient.

The final device selection will be dependent on 3 factors:

- the dental professional performing the procedure,
- the patient undergoing treatment,
- the type of procedure being performed.

**INTENDED USERS**

All devices are intended to be used by a qualified dental professional.

**LIFETIME OF THE DEVICE**

The lifetime of the device is normally determined by wear and tear and not through re-processing and depends on several factors and actions being carried out by the end user including: -

- the correct procedures being followed for sterilisation of the device prior to use,
- the instructions for use being followed correctly to avoid damage occurring to the instrument and/or patient,
- the condition of the handpiece being used,
- possible solutions being used with the product,
- the device being inspected for defects following preliminary cleaning.

Perfection Plus products are tested and certified as both safe and usable within the date parameters set by the use by dates as indicated on the product labelling. Whilst we would not expect any real degradation of the product, we cannot guarantee its safety beyond the use by date and would strongly recommend that the products are disposed of in accordance with the local regulations. The use by date set for these devices is 5 years from the date of manufacture. The 5-year lifespan has been concluded from the inspection tests for dimensional checks, shank/mandrel critical connection checks and shelf-life tests conducted on products over 5 years old and the product performing correctly and without failure demonstrating the 5-year shelf life is acceptable.

The devices are manufactured and packaged in such a way that no deterioration can occur which could compromise the safety of the patient, user or other persons or the performance of the product.

**BATCH CODE/ EXPIRY DATE**

The batch code is shown as LOT. Please quote this in all correspondence. The manufacturing date and expiry date are shown in month, year format. Do not use the product after the expiry date.

**SAFETY PRECAUTIONS**

These dental instruments were developed and manufactured for their specific dental application. Incorrect use may harm tissue, cause premature wear, destroy the Instrument, and endanger the operator, patient or third parties.

**WARNINGS**

Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.

These devices contain small amounts of nickel and should, therefore, not be used on individuals with a known sensitivity to this metal as in extreme cases it may cause hypersensitivity.

**CAUTION**

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

**SYMBOLS USED**

Pack size


Perfection Plus Ltd
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