

## 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	PP005/6002	Prophy+ Latex Free Cups RA Purple Medium pk 720
PP005/0008	Prophy+ Brushes Bristle RA pk 144	PP005/5603	Prophy+ Latex Free Cups Screw- In Blue Hard pk 50
PP005/3004	Prophy+ Brushes Bristle RA pk 150	PP005/6103	Prophy+ Latex Free Cups Screw- In Blue Hard pk 720
PP005/5430	Prophy+ Brushes Bristle RA pk 50	PP005/5601	Prophy+ Latex Free Cups Screw- In Pink Soft pk 50
PP005/0060	Prophy+ Brushes Bristle RA pk 720	PP005/6101	Prophy+ Latex Free Cups Screw- In Pink Soft pk 720
PP005/0031	Prophy+ Brushes Bristle Screw-In pk 100	PP005/5602	Prophy+ Latex Free Cups Screw- In Purple Medium pk 50
PP005/3003	Prophy+ Brushes Bristle Screw-In pk 150	PP005/6102	Prophy+ Latex Free Cups Screw -In Purple Medium pk 720
PP005/5431	Prophy+ Brushes Bristle Screw-In pk 50	PP005/5703	Prophy+ Latex Free Cups Snap- On Blue Hard pk 50
PP005/0004	Prophy+ Brushes Nylon RA pk 100	PP005/6203	Prophy+ Latex Free Cups Snap -On Blue Hard pk 720
PP005/0006	Prophy+ Brushes Nylon RA pk 144	PP005/5701	Prophy+ Latex Free Cups Snap -On Pink Soft pk 50
PP005/3005	Prophy+ Brushes Nylon RA pk 150	PP005/6201	Prophy+ Latex Free Cups Snap- On Pink Soft pk 720
PP005/0016	Prophy+ Brushes Nylon RA pk 36	PP005/5702	Prophy+ Latex Free Cups Snap- On Purple Medium pk 50
PP005/5435	Prophy+ Brushes Nylon RA pk 50	PP005/6202	Prophy+ Latex Free Cups Snap- On Purple Medium pk 720
PP005/0065	Prophy+ Brushes Nylon RA pk 720	PP005/0010	Prophy+ Polishing Cups RA pk 100
PP005/1002	Prophy+ Brushes Nylon RA Blue Hard pk 50	PP005/0009	Prophy+ Polishing Cups RA pk 144
PP005/1000	Prophy+ Brushes Nylon RA Pink Soft pk 50	PP005/3002	Prophy+ Polishing Cups RA pk 150
PP005/1001	Prophy+ Brushes Nylon RA Purple Med pk 50	PP005/0013	Prophy+ Polishing Cups RA pk 50
PP005/2003	Prophy+ Brushes Nylon Screw- In Blue Hard pk 50	PP005/0039	Prophy+ Polishing Cups RA pk 720
PP005/2001	Prophy+ Brushes Nylon Screw -In Pink Soft pk 50	PP005/0037	Prophy+ Polishing Cups Rubber Screw In pk 720
PP005/0030	Prophy+ Brushes Nylon Screw- In pk 100	PP005/0033	Prophy+ Polishing Cups Screw In pk 100
PP005/3006	Prophy+ Brushes Nylon Screw- In pk 150	PP005/0002	Prophy+ Polishing Cups Screw In pk 144
PP005/2002	Prophy+ Brushes Nylon Screw In Purple Med pk 50	PP005/3000	Prophy+ Polishing Cups Screw In pk 150
PP005/5503	Prophy+ Latex Free Cups RA Blue Hard pk 50	PP005/5433	Prophy+ Polishing Cups Screw In pk 50
PP005/6003	Prophy+ Latex Free Cups RA Blue Hard pk 720	PP005/0032	Prophy+ Polishing Cups Snap On pk 100
PP005/5501	Prophy+ Latex Free Cups RA Pink Soft pk 50	PP005/0001	Prophy+ Polishing Cups Snap On pk 144
PP005/6001	Prophy+ Latex Free Cups RA Pink Soft pk 720	PP005/3001	Prophy+ Polishing Cups Snap On pk 150
PP005/5502	Prophy+ Latex Free Cups RA Purple Medium pk 50	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 *preventive* procedures, including the cleaning and polishing of natural teeth, gold and amalgam fillings, composites, compomers and glass ionomer cements, *and the removal of plaque, tartar and stains caused by diet and smoking, with the desired goal of preventing and/or alleviating further progression of oral infections, dental diseases such as tooth decay and gingivitis and bad breath.*

#### **INSTRUCTIONS FOR USE**

These Class *Ila* medical devices are for use in the *oral cavity* only, by, or under the instruction of a qualified dental professional and are manufactured in accordance with the ISO 1797 Std. *They should only be used in conjunction with a clean, well maintained rotary hand piece that that can be either air, or electrically driven and that conforms to the ISO 14457 Std. For*

*the RA and Screw-In cups a slow speed hand piece should be used, whilst for the Snap-On cups a lightweight prophylaxis hand piece should be used. For the Screw-In and Snap-On cups a dental mandrel is used to connect the device to the dental hand piece. The specific make and model used is a decision ultimately made by the end user, an appropriately qualified dental professional. Likewise, the choice of prophylaxis paste will be made by the end user and determined by the structure of the tooth and the restorative material being worked on. Perfection Plus's range of prophylaxis brushes and polishing cups can be safely used with fine, medium and coarse grit pastes.*

*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 *cleaning/disinfecting and* sterilisation processes was 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 Industry Association (BDIA).

*For the purposes of this validation the following equipment/disinfecting agent was used:*

*Miele Thermal Disinfector with Mediclean Neodisher  
Getinge GE 224Vac Autoclave (vacuum & non-vacuum)  
Gallenkamp Hot Air Oven*

*Due to the wide variety of commercially available disinfectant agents, if their use in preparation for cleaning is to be advocated, they must be CE marked and validated for the processing of dental instruments. In all cases the disinfectant manufacturer's instructions must be adhered to.*

### **STERILISATION**

The devices are intended and indicated for single use only, and the instructions therefore apply before first use only. *The devices are supplied mechanically clean but not sterile and, should therefore be sterilised prior to use.*



### **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.

### **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 disinfectant 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 134°C.



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 hand pieces are maintained in good working order and remain lubricated to ensure maximum effectiveness of the device.*
- 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 making contact with the targeted tooth.*
- 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 and a respiratory mask to prevent inhaling any dust and/or debris during the procedure.*
- 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 other* CE marked medical devices (i.e. prophylaxis paste, *dental hand pieces and 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**

- *Do not apply excessive pressure as this could result in the build-up of undesirable heat and damage to the instrument.*

## **RECOMMENDED SPEEDS**

- Maximum Speed 10,000 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.*
- Keep within the speed range of the product being used for the best work results.

## **INTENDED PATIENT GROUPS/INTENDED PURPOSE**

The devices are intended for use on patients of any age *as required, subject to user opinion where appropriate*. 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**

*As indicated on product labelling these devices are indicated for single-use only and should therefore not be re-used. The performance and efficacy of the device can be influenced by the actions of 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 eliminate and/or reduce avoidable damage to the device*,
- the condition of the handpiece being used,
- *use of appropriately proven detergents validated for processing dental instruments*,
- the device being inspected for defects before *and after cleaning/sterilising*.

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.

#### **CONTRAINDICATIONS**

*Perfection Plus prophylaxis polishing cups\* and brushes contain a small nickel content and should therefore not be used on individuals with a known sensitivity to this metal, as in extreme cases it may cause hypersensitivity.*

*\*excludes the snap-on cups*

#### **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 are indicated and intended for single-use only. As per the findings from the validation conducted by the University of Liverpool, contaminated prophylaxis brushes and polishing cups could not be cleaned sufficiently by thermal disinfection to achieve sterility in an autoclave or hot oven. Therefore, the risk of cross-infection whilst unlikely, remains a possibility.*

*Failure to properly maintain the hand piece can lead to procedural delays and compromised device performance.*

*Never exceed the maximum speed limit as this can induce vibration resulting in possible damage to tooth structure and the gumline, and potential breakages and ingestion of the device.*

*Overzealous and repeated polishing can in some instances result in wearing of the superficial tooth structure.*

#### **CAUTION**

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

#### **SYMBOLS USED**



Qty per Pack



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