

**PRODUCT:** Rubber Prophy minicups RA

**MANUFACTURER:** PERIDENT DENTAL PRODUCTS S.R.L.

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**Classification:** Class IIa Medical Device – (single-use device)

*Professional use only*

Rubber Prophy minicups are for use by the Dentist or Hygienist for prophylaxis polishing of teeth, they are for single use only. These instruments are Class 2a Medical devices and are for use in the mouth only by (or under the instruction of) a qualified dental professional. They 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.

## Proper use

- Only use hand piece, angles and turbines that are technically and hygienically flawless, maintained and cleaned.
- These polishers are for single use only. Do not reuse.
- Turbine and hand piece must be concentric and true running.
- The instruments must be inserted as deeply as possible into the hand-piece and locked.
- Avoid tilting or levering because of the increased risk of breakage.
- Instruments that are deformed or no longer run true should not be used and must be disposed of.
- Always wear safety goggles.
- Wear a face mask to prevent biological transfer.
- Incorrect use produces poor results and increases the risk.
- These products must only be used by qualified staff.

## Safety precautions

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

## Pressure

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

Excessive pressure may cause overheating which injures the pulp or damage the rubber minicups. In extreme cases, the instrument may even break, which may cause injury.

## Recommended speeds

- Keep within the speed range of 5,000 – 10,000 rpm for the best work results and to increase the service life of the instrument.
- 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.

## **Dispose of worn instruments**

- Worn or damaged minicups may cause vibration.
- Bent or non-concentric instruments must also be disposed of.

Worn rotary instruments induce the user to exert more pressure, which increases the working temperature. This may injure the pulp or tooth.

## **Intended purpose**

The devices are intended for use on both adolescents and adults. The products are only aimed as a tool for use by the dental professional who is responsible for determining the treatment required by each individual patient and which treatment would outweigh the risks of performing.

The final polisher selection will be dependent on 3 factors:

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

## **Intended Users**

All devices are intended to be used by professionally qualified and trained Dental Surgeons and Hygienists.

## **Intended Clinical Use**

The devices are indicated for use by dental professionals for a wide range of restorative procedures, including the cleaning and polishing of natural teeth, gold and amalgam fillings, composites, compomers and glass ionomer cements for removing plaque and stains. The devices may be used in combination with prophylaxis polishing pastes.

No other materials, substances or gases are used within the device.

The conditions on which the products are used are for plaque removal, tartar removal, general cleaning of stains and to ensure areas are clean prior to fillings and procedures.

The devices are single use.

## **Storage, disinfection, cleaning and sterilization**

### **Scope**

These instructions are applicable to the processing of dental rotary instruments before first use. Dental rotary instruments are supplied mechanically clean but are not sterile. They should therefore be sterilized before first use. Rubber minicups are single use devices and the instructions therefore only apply to processing before first use.

### **Warnings**

Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken during processing. 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.

If a single use device was re-used, there is a risk of infection or transference of disease from one patient to another; therefore, it is essential that good procedures are followed.

### **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 rubber polishers 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 rubber polishers with the selected machine. Follow the washer disinfectant and the cleaning agent manufacturers' instructions.

If hand cleaning is the only available option, the minicups should be cleaned in a sink reserved for the purpose. Rinse the minicups under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent validated for use on dental rotary instruments. Follow the agent manufacturers' instructions. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration.

After cleaning inspect the rubber polishers, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

### **Drying**

Dry the polishers using paper towelling.

### **Inspection**

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

### **Packaging for sterilization**

If using a vacuum autoclave pack the minicups in dedicated instrument trays or pouches validated for sterilization.

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

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

### **Sterilization**

Autoclave the instruments for a holding time 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. In particular care must be taken not to exceed the maximum recommended load for the autoclave.











### **Storage**

The rubber polishers should be stored in the sterilization container 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 the rubber minicups for use by or under the supervision of a qualified person. It remains the responsibility of the processor to ensure that the processing as actually performed using the equipment, materials and personnel in the processing facility 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.

**Symbols used in the product label:**

	Reference number
	Batch code
	Do not re-use. Disposable device to be used only once on a single patient. Re-use may lead to severe cross infections.
	Use by
	Manufacturer
	Consult Instructions for use
	Keep away from sunlight
	Keep dry
	Wear safety goggles
	Recommended speed