Sterilisation and Instructions for Use

CE 0425

PRODUCT: Rubber prophy minicups (latch, snap-on and screw type)

MANUFACTURER: PERIDENT DENTAL PRODUCTS S.R.L.
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Classification: Class IIa Medical Device – (single-use device)

Professional use only

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.

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.

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.
The devices are sold non-sterile and must be cleaned and sterilised by the qualified dental professional prior to use.

Lifetime of the device (single use device)
The lifetime of the single device (during the single prophylaxis procedure) is normally determined by wear and tear and and depends on a number of 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.

The instruments are intended as single use devices and the instructions therefore apply before first use.
The devices are tested and certified as safe and usable if used by the expiration date indicated on the product label.
After this date, the safety of the device can no longer be guaranteed and the disposal of the device in accordance with the regulations in force is strongly recommended.

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 lubricated at all times 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 to avoid making dents.
- Avoid tilting or levering because of the increased risk of breakage.
- Only use top quality instruments to avoid breakage and injury. 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.
- Always wear safety goggles. Holders, mandrels and shafts or the workpiece being polished can break when used incorrectly or when the material has flaws and become dangerous flying objects.
- Wear a respiratory mask to prevent inhaling any dust and/or debris during the procedure.
- 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.
- These products must only be used by qualified dental professional.
- (Snap-On devices only) To ensure vibration-free working the connected instrument must be centred after mounting on the mandrel or shaft. Only use top quality mandrels and holders to avoid breakage and injury. Any damaged and incorrectly shaped instruments will cause vibration. Bent or non-concentric instruments must be disposed of.

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

Avoid excessive pressing force.

- 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.

Worn rotary instruments induce the user to exert more pressing force which increases the working temperature and thus damage the tooth structure or pulp. In the worst case, it is not possible to rule out the risk of the instrument breaking, which can cause injuries.

Recommended speeds

- Maximum speed 10,000 rpm.
- Keep within the following speed range of 1,500 – 10,000 rpm for the best work results and to increase the service life of the instrument.
- Never exceed the maximum permitted speed of the product. The recommended speeds and maximum permitted speeds vary from product to product. Always check the recommended speed as stated on the label and in the instruction for use.
- 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 and to increase the service life of the instrument.
- Failure to comply with the maximum permitted speed produces an increased safety risk.

Dispose of worn instruments

The devices are single use type and must be disposed of after their only intended use. Furthermore:

- If the instruments show wear that does not allow compliance with the treatment parameters or are damaged during the dental prophylaxis procedure, they must be replaced with new devices as they can cause excessive vibrations and lead the user to exert greater pressure, thus causing an increase in the operating temperature, with the risk of damaging the dental pulp or the tooth structure.
- You must stop using instruments that bend or lose their concentricity during the procedure and must also be immediately replaced and disposed of.

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 and which treatment would outweigh the risks of performing.

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 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.

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

The maximum number of repeat applications required is determined by the qualified dental professional. The area of contact within the mouth is the teeth.

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 in accordance with these Instructions for Use. The instruments 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 not allowed to be used for more than one patient procedure.

The devices contain small amounts of nickel and, therefore, should not be used on individuals with a known sensitivity to this metal, as in extreme cases it can cause hypersensitivity. Generally, during the use of the device there is little or no contact and the risk of allergy can be considered negligible; however, the practitioner is advised to find this allergy in the patient medical history questionnaire to be completed before using the device.

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 prophy minicups 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 dental prophy minicups with the selected machine. Follow the washer disinfector and the cleaning agent manufacturers' instructions.
If hand cleaning is the only available option, the device should be cleaned in a sink reserved for the purpose. Rinse the instrument 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 instruments, 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 minicups, with the aid of magnification if necessary, and discard any damaged or corroded instruments.

Packaging for sterilization

If using a vacuum autoclave pack the instruments in dedicated instrument trays or pouches validated for sterilization.
If using a non-vacuum autoclave the device 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 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. In particular care must be taken not to exceed the maximum recommended load for the autoclave.

Storage of sterilised instruments

The device should be stored in the sterilisation container until the treatment efficacy expires. 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 dental minicups for use. 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:

REF	Reference number
LOT	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 googles
	Recommended speed