

PRODUCT: Mandrels (RA) for brushes and minicups (snap-on and screw type)

MANUFACTURER: PERIDENT DENTAL PRODUCTS S.R.L.

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

Professional use only

These instruments are Class IIa 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.
- Turbine and hand piece must be concentric and true running.
- The instruments must be clamped as deeply as possible.
- 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.
- Instruments that are deformed or no longer run true should not be used and must be disposed of.
- 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.
- 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.
- Incorrect use produces poor results and increases the risk. These products must only be used by qualified staff.

Recommended speeds

- Never exceed the maximum permitted speed of the product mounted to the mandrel. The recommended speeds and maximum permitted speeds vary from product to product. Always check the recommended speeds on the product packaging.
- If you exceed the maximum permitted speed, the polishers tend to vibrate, which can cause destruction to the shaft and/or make the instrument break, with a risk to the user, the patient or third parties. This is why you must never exceed the maximum permitted speed.
- Keep within the speed range of the product being used for the best work results and to increase the service life of the tools.
- Failure to comply with the maximum permitted speed produces an increased safety risk.

Pressing forces

- Avoid excessive pressing force.
- In polishing instruments, excessive pressing forces can cause the sanding elements to break or make the instrument smear, resulting in excessive heat development.

Excessive pressing forces can overheat 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.

Storage, disinfection, cleaning and sterilization

Scope

These instructions are applicable to the processing of mandrels before first use and each reuse. Dental rotary instruments are supplied mechanically clean but are not sterile. They should therefore be sterilized before first use.

Warnings

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

Limitations of processing

Reprocessing will have little effect on mandrels. The end life is determined by wear and damage in use and the instrument should be inspected for defects during the preliminary cleaning process.

Containment at the point of use

Unless there is specific infection or cross-contamination risks, there are no special requirements for containment. The instrument can be transported wet or dry. 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 mandrels 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 mandrels with the selected machine. Follow the washer disinfectant and the cleaning agent manufacturers' instructions.

If hand cleaning is the only available option, the instrument should be cleaned in a sink reserved for the purpose. Rinse the mandrels 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 mandrels. 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 mandrels, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

Drying

Dry the instrument using paper towelling or dry heat not exceeding 140°C.

Inspection

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

Packaging for sterilization

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

If using a non-vacuum autoclave the mandrels should not be packed or wrapped but be contained in dedicated 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 instrument 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 mandrels for reuse. It remains the responsibility of the processor to ensure that the reprocessing 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
	Use by
	Manufacturer
	Consult Instructions for use
	Keep away from sunlight
	Keep dry
	Wear safety goggles