

Dental Polishers (sterile/non-sterile)

INSTRUCTIONS FOR USE

DESCRIPTION: Prima Dental Manufacturing Ltd range (Illume) of new precision manufactured rotary Dental Polishers have been designed with patient comfort and satisfaction very much to the forefront. With a wide range of shapes, sizes and shanks in the product portfolio, our range of Illume dental polishers allows the user to adjust and polish ceramics, composites, acrylics, alloys and gold. Illume dental polishers come in either a fine grit finish (shine), medium grit finish (polish) or coarse grit finish (reveal). Refer to the Prima Dental product brochure (welcome to a brighter future – new products 2015) and the Company website (www.primadental.com).

SCOPE: These instructions are applicable to both sterile and non-sterile dental polishers as offered by the Company.

Dental polishers identified as such ^② are single-use devices and should therefore NOT be re-processed!

INDICATIONS FOR USE: Prima Dental Group dental polishers are intended for prophylactic, conservative and prosthetic dentistry, to grind and/or polish natural or restorational dental materials. The polisher pattern selected will be chosen from the recommendations as shown in the matrix below.

Product Type	Zirconia	Ceramic	Composite	Alloys	Precious Metal/Amalgam	Bracket Removal
Single-use Composite			xx			
2 Step Composite			xx			
3 Step Basic Alloy			x	x	xx	
Bracket Removal						xx
3 Step Zirconia	xx	x				
3 Step Ceramic		xx		x		
3 Step Denture Acrylic				xx		

Key: Recommended (xx)
Suitable (x)

The polishers **MUST** be running at the required speed (min 6,000/max 20,000 rpm) before making contact with the surface being treated. To avoid dents, use a slightly circular motion when polishing.

Ensure a sufficient supply of air/water spray (50ml/min minimum) at all times in order to dissipate a build-up of heat caused by friction. **Insufficient water cooling may cause irreversible damage to the tooth and adjacent tissue!**

On the proviso that the teeth being treated are considered suitable, there are no restrictions on the intended patient population.

CONTRAINDICATIONS & WARNINGS: No known contraindications. Used polishers shall be considered as contaminated and as such, appropriate handling and disposal procedures must be followed when discarding used polishers. **In the event of polishers being returned to Prima Dental Manufacturing Ltd, please ensure any contaminated and/or potentially contaminated polishers have been effectively cleaned, and are appropriately packaged for return.**

STORAGE: Store in a dry and clean environment at room temperature (15-25°C). Store out of direct sunlight and away from other sources of heat.

PRECAUTIONS:

Eye protection shall be worn to protect eyes against ejected particles.

Surgical masks and/or a respirator shall be worn to avoid inhalation of dust generated during the procedure.

Prior to use inspect the polisher for signs of damage (cracks, chips).

Ensure the polishers are fully seated and gripped in the hand-piece collet. Check for run-out so as to avoid unwanted vibration during use.

Never exceed the maximum speed, refer to information printed on product label. **Exceeding the maximum permissible speed limit will significantly increase the risk of injury to the patient, user or other third party. For this reason, the permissible maximum speed limit must NOT be exceeded under any circumstances!**

Do NOT cant or pry as it could lead to an increased risk of fracture.

Avoid excessive contact pressure as this may damage the polisher and result in a potential build-up of heat, causing injury to the pulp and undesirable roughness to the surface finish. In extreme cases, the polisher could break causing further risk of injury!

PREPARATION FOR CLEANING: The following sections for re-processing are applicable to **non-sterile** polishers **only!**

Sterile polishers identified as single-use ^② are not intended for reuse and must be disposed of following initial use! Refer to page 2 for recommended cleaning processes (ref manual & mechanical cleaning).

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CLEANING: As per the requirements of ISO17664 (Sterilisation of Medical Devices – information to be provided by the manufacturer for the processing of resterilisable medical devices) the following sections apply to the manual and mechanical re-processing of used dental polishers.

Note – new, non-sterile supplied devices MUST be treated before use!

Process	MANUAL Treatment	MECHANICAL Treatment
Preparation	Immerse the devices in cold water for a minimum of 5 mins immediately after use.	Immerse the devices in cold water for a minimum of 5 mins immediately after use. Rinse thoroughly under running water, remove stubborn contamination with a nylon brush.
Cleaning/Disinfection	Rinse thoroughly under running water, remove stubborn contamination with a nylon brush. Clean and chemically disinfect with a suitable solution (i.e. Komet DC1) in an ultrasonic device at 40°C (manufacturers information regarding material biocompatibility must be considered). Rinse devices thoroughly under running water.	Place devices in a suitable rack or bur block. Place the rack/bur block (lid open) in the washer/disinfector in such a way so as to ensure the maximum contact with the spray jet. Add the appropriate cleaning agent as per the manufacturer's recommendations and the instructions given with the washer/disinfector. Commence the relevant programme (i.e. pre-treat with cold water for a minimum of 2 mins, clean with tap water for 5 mins at 55°C and 0.5% rinsing solution, neutralise for 3 mins with demineralised water, rinse for 2 mins with demineralised water and drain).
Drying	Dry instruments, preferably with compressed air.	On completion of the cleaning/disinfection cycle remove instruments from the washer/disinfector and (if evident) remove any residual moisture, preferably with compressed air. Ensure the device is thoroughly dry.
Visual Inspection	Check cleanliness and integrity, in case of remaining residual contamination, the cleaning/disinfection process must be repeated. Sort out and remove any defective devices (ref chipped/cracked elements, corroded surfaces).	Check cleanliness and integrity, in case of remaining residual contamination, the cleaning/disinfection process must be repeated. Sort out and remove any defective devices (ref chipped/cracked elements, corroded surfaces).
Thermal Disinfection in Steam Steriliser	In sterilisation bags, or without barrier systems. In suitable racks, trays etc. 3 pre-vacuum pulses at 134°C for 3 mins with an additional 1 minute drying time.	In sterilisation bags, or without barrier systems. In suitable racks, trays etc. 3 pre-vacuum pulses at 134°C for 3 mins with an additional 1 minute drying time. Note – thermal disinfection may be omitted by verifiable usage of the washer/disinfector.
Approval	Documented approval of the cleaning process in order to reuse and/or store the devices.	Documented approval of the cleaning process in order to reuse and/or store the devices.
Storage	Store in a dust-free, dry environment protected against possible sources of contamination.	Store in a dust-free, dry environment protected against possible sources of contamination.

Limitation of Re-processing: The life of the product is normally determined by wear and tear and NOT by re-processing!

LOT NUMBER: The Lot or batch number is a seven (7) digit number printed on the label and the packaging. **This number must be quoted in any correspondence.**

POST MARKET FEEDBACK: As part of our documented QMS and continuing commitment to monitor and act on post market feedback, Prima Dental welcome any feedback regarding the appearance and performance of our products and packaging. If you have any comments you wish to make, please contact us by writing to or e-mailing us at the address given below. Please communicate the Lot No in all correspondence.

Rx ONLY (ref US FDA CDRH)



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