

Dental Mirrors REPROCESSING INSTRUCTIONS

1.0 DESCRIPTION:

Perfection Plus's range of re-usable hand-held dental mirrors are non-powered stainless steel instruments comprising a glass lens attached to a frame with a stem (mirror head) that is connected to a handle via an internal screw thread.

The dental mirrors are designed to perform specific functions within the oral cavity to assist the user in achieving a clear uninterrupted view during a dental procedure.

The range includes both front and rear (plane) surface mirrors with either round or octagonal handles.

2.0 SCOPE:

These instructions are applicable to the reprocessing of Perfection Plus's range of stainless steel hand-held dental mirrors, prior to initial use and after each subsequent re-use. Perfection Plus dental mirrors are supplied mechanically clean but are NOT sterile, and therefore must be cleaned and sterilised before use.

The person performing the reprocessing is responsible for ensuring that the equipment used is safe and validated for cleaning, disinfecting and sterilising stainless steel instruments. Equipment used for the purposes of reprocessing must be properly maintained and regularly checked as per the equipment manufacturer's instructions and recommendations.

3.0 INDICATIONS FOR USE:

Perfection Plus's range of hand-held dental mirrors are intended for use by appropriately qualified dental professionals for all types of dental procedures where the user requires clearer visibility of the operative field.

Dental mirrors must only be used for their intended purpose.

4.0 STORAGE (pre-use):

The dental mirrors should be retained in their original packaging and kept in a dry, clean and well-maintained environment until needed.

5.0 INITIAL TREATMENT at POINT of USE:

Pre-use, dental mirrors must be checked for any obvious signs of damage and/or deterioration particularly to the glass lens, any found in a condition which causes concern, must be segregated and Perfection Plus notified as per the contact details on page 3.

Post use, remove any heavy soiling with a cloth/paper wipe or a soft-bristle brush. Do not allow fluids to dry on the surface of the glass lens. Never use abrasive cleaners or brushes with hard bristles as this may cause discolouration, pitting or scratching that could result in corrosion. Delays in re-processing must be kept to an absolute minimum to avoid contaminants drying and making cleaning more difficult.

When reprocessing used dental mirrors always handle with care and caution and wear protective clothing, gloves and safety glasses in accordance with local health & safety protocols and procedures.

6.0 PREPARATION BEFORE CLEANING:

Inspect dental mirrors visually for any obvious signs of damage and/or deterioration, particular attention must be paid to the glass lens which should be free of cracks, chips and scratches and be seated securely within its frame. Refer also to Section 16.0 (Pre-cautionary Measures & Monitoring of Functionality).

7.0 MANUAL CLEANING:

Whilst automated cleaning is the preferred option, if manual cleaning is the only choice, dental mirrors must be cleaned in a sink specifically reserved for this purpose.

- 7.1 dental mirrors can be processed in either an assembled or disassembled state. If processed disassembled refer to Section 9.0 (Inspection & Maintenance) when reassembling,
- 7.2 wearing a pair of protective gloves, carefully rinse the instruments under running potable water for at least 1 minute using a soft-bristle brush to remove any coarse impurities,
- 7.3 prepare a fresh bath using an aldehyde free alkaline cleaning/disinfectant agent with a pH of 10 following the suppliers instructions, ref concentration & duration. Soak the mirrors ensuring all are fully immersed. Never leave the mirrors in disinfectant solutions for extended period of times,
- 7.4 using a soft-bristle brush thoroughly clean the mirrors, including the transitions and threaded sections brushing away from the body,
- 7.5 remove the mirrors from the cleaning solution and thoroughly rinse with fully desalinated/de-ionised water for at least 1 minute in order to prevent the build-up of limescale residues which leave behind white deposits or water spots,
- 7.6 visually inspect the mirrors to ensure all contaminants/debris has been removed, repeat steps if necessary,
- 7.7 dry the mirrors using a lint free cloth or compressed air. Never store wet/damp mirrors, they must be thoroughly dry,
- 7.8 visually inspect the mirrors to ensure all contaminants/debris has been removed, repeat if necessary.

Dental mirrors are not suitable for ultrasonic cleaners.

8.0 AUTOMATED CLEAN/DISINFECT:

Use only CE-marked and appropriately maintained washer disinfectors validated as suitable for cleaning and disinfecting soiled stainless

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steel instruments.

- 8.1 wearing a pair of protective gloves carefully load the dental mirrors into a suitable instrument rack or sieve tray,
- 8.2 carefully place the instrument rack or sieve tray into the washer disinfectant and start the programme following the equipment manufacturer's recommendations,
- 8.3 after the initial wash cycle use an enzymatic mildly alkaline detergent to break down any remaining adherent soiling,
- 8.4 for the disinfect cycle use an aldehyde free alkaline cleaning/disinfectant agent with a pH of 10, following the suppliers instructions, ref concentration and duration,
- 8.5 remove the mirrors from the washer disinfectant and dry with compressed air,
- 8.6 visually inspect to confirm removal of all contamination/debris, repeat cycle if necessary. Carefully inspect the instruments for any signs of damage and/or deterioration, discard any which appear faulty.

When using an automated washer disinfectant, the user shall ensure that the process has been validated with the selected cleaning and disinfecting agents. Any cleaning and disinfecting agents used must be compatible with stainless steel.

9.0 INSPECTION & MAINTENANCE:

To ensure the continued functionality and safe performance of the dental mirrors, regularly inspect for signs of damage and/or deterioration and corrosion. Any found in a condition which causes concern must be immediately discarded.

When processed in a disassembled state, when re-attaching the dental mirror to its handle, always hold the mirror head by its stem - never the lens. You can then attach and firmly tighten the mating sections without the risk of damaging/deforming the weld and/or frame which could compromise the security of the glass lens.

10.0 PACKAGING:

Ensure dental mirrors are completely dry before packaging, then package the clean disinfected mirrors immediately. We recommend the use of Perfection Plus Self-Seal Sterilisation Pouches, the pouch must be large enough to ensure there is no undue stress placed on the seal. Sterilisation wraps or suitable sterilisation containers can also be used if the following requirements are fulfilled:

- 10.1 suitable for steam sterilisation, temperature resistance up to at least 141°C (286°F),
- 10.2 afford sufficient steam permeability,
- 10.3 afford sufficient protection of the instruments and the sterilisation packaging against mechanical damage.

11.0 STERILISATION:

Use only CE-marked and appropriately maintained autoclave units validated as suitable and effective for sterilising stainless steel instruments.

To prevent the build-up of limescale deposits and/or water spots, prior to placing in the autoclave, ensure the mirrors are thoroughly dry.

- 11.1 wearing a pair of protective gloves, carefully load the mirrors either singularly⁽ⁱ⁾ or in sets⁽ⁱⁱ⁾ into the chamber of the autoclave unit.
 - (i) carefully pack mirrors into pouches validated for steam sterilisation. Ensure the pack is large enough to contain the instruments without stressing the seals.
 - (ii) load the mirrors into dedicated instrument trays or general-purpose sterilisation trays. When loading, place any heavier instruments to the bottom of the tray on top of a cotton cloth or towel.
- 11.2 switch on the autoclave unit and when the temperature reaches 134°C, maintain exposure for 5 minutes,
- 11.3 turn off the autoclave unit and allow the instruments time to cool down before handling. Autoclaves with an automated drying programme are preferred, 10 minutes being the recommended drying cycle,
- 11.4 NOTE - when sterilising multiple instruments in one cycle, ensure that the autoclave manufacturer's stated maximum load is NOT exceeded,

The manufacturer's instructions with regards to the routine inspection and maintenance of the autoclave unit must be observed and adhered to at all times.

12.0 STORAGE:

Sterile mirrors must be stored in a dry, clean dust-free environment. Product sterility can only be maintained if the instruments remain packaged or wrapped, impermeable to micro-organisms.

The sterilisation status must be clearly indicated on the wrapped packages or on the containers. For safety reasons ensure sterile and non-sterile instruments are kept well apart.

13.0 CONTAINMENT & TRANSPORTATION:

Once used it is recommended that mirrors are reprocessed immediately. To prevent damage and/or deterioration during transportation, mirrors should be stored in either a dedicated instrument tray or closed container. To minimise the risk of cross contamination, avoid storing clean and soiled mirrors in the same instrument tray or container.

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14.0 WARNINGS & PRECAUTIONS:

- 14.1 always follow the instructions and warnings given by the manufacturer of any reprocessing equipment/chemicals used,
- 14.2 mirrors must be thoroughly cleaned and processed prior to first use and after each subsequent re-use,
- 14.3 mirrors must be inspected prior to reprocessing for signs of any damage and/or deterioration which could compromise functionality and performance. All faulty mirrors must be immediately discarded. Disassembled mirrors shall be inspected for functionality after re-assembly,
- 14.4 if manually cleaning, do not use metal brushes, always use a soft bristle brush,
- 14.5 do not apply excessive force, the glass lens is fragile and liable to chip or crack,
- 14.6 avoid using short autoclave programmes with high temperature changes - glass has a different coefficient of expansion to stainless steel, a quick and high temperature change can cause stress to the glass and lead to cracks and breakages,
- 14.7 mirrors are not suitable for ultrasonic cleaners,
- 14.8 mirrors must not be exposed to saline and cleaning/disinfection agents containing corrosive materials. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used,
- 14.9 coarse impurities must be removed from the mirrors immediately, do not allow biological soiling to dry onto contaminated mirrors, as it may compromise the effectiveness of the cleaning, disinfecting and sterilising processes,
- 14.10 appropriate Personnel Protective Equipment (PPE) should be worn when handling contaminated/potentially contaminated dental mirrors.

15.0 LIMITATIONS & RESTRICTIONS on REPROCESSING:

The working life of a dental mirror depends on a number of factors, including its frequency of use, the reprocessing methods undertaken and the care of the user.

16.0 PRE-CAUTIONARY MEASURES & MONITORING of FUNCTIONALITY:

- 16.1 to avoid compromising the integrity and security of the glass lens, during use refrain from applying excessive pressure. The use of a rubber dam is recommended, especially when using on children and problematic patients,
- 16.2 prior to initial use and subsequent re-use, check the condition of the mirror, in particular:
 - a/ check the integrity of the joint connecting the mirror head to the handle/stem,
 - b/ check the glass lens sits snugly and tightly in the frame,
 - c/ check for cracks, chips and scratches which could compromise the use of the device and patient safety.

Any faulty mirrors must be segregated and returned to Perfection Plus for investigation.

17.0 DISPOSAL:

Used and end of life dental mirrors shall be disposed of as clinical waste in accordance with the National regulations of the user territory.

18.0 LOT NUMBER:

The Lot or batch number can be found printed on product labelling. This number must be quoted in any correspondence.

19.0 POST MARKET FEEDBACK:

As part of our documented QMS and continuing commitment to monitor and act on post market feedback, Perfection Plus 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 the address shown below or e-mailing us at sales@perfectionplus.com. Please communicate the Lot No in all correspondence.

In the event of dental mirrors being returned to Perfection Plus, please ensure any contaminated and/or potentially contaminated mirrors have been effectively cleaned and are appropriately packaged for return.

For more information on the full range of dental mouth mirrors available, contact Perfection Plus at sales@perfectionplus.com or visit our website at www.perfectionplus.com



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