Perfection Plus

Re-usable Hand-Held Instruments
REPROCESSING INSTRUCTIONS

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1.0 DESCRIPTION
Perfection Plus's range of re-usable hand-held instruments are non-powered instruments comprising of both fixed and simple hinged assemblies that have been designed to perform specific functions such as cutting, scraping, grasping, retracting, clamping, probing and aspirating.

The range includes instruments for use in dental, chiropody and veterinary applications.

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

2.0 SCOPE
These instructions are applicable to the reprocessing of Perfection Plus's range of hand-held instruments, prior to initial use and after each subsequent re-use. Perfection Plus instruments are supplied mechanically clean but are NOT sterile, and therefore must be cleaned and sterilised before use. Instruments having hinged joints, metal contacts and moving parts must be lubricated prior to use, ref section 14.0

3.0 INDICATIONS FOR USE
Perfection Plus's range of hand-held instruments are intended for use in diagnostic, restorative, surgical, laboratory and/or hygienic procedures by appropriately qualified professionals in the fields of dentistry, chiropody and veterinary. The instruments must only be used for their intended purpose.

4.0 WARNINGS & PRECAUTIONS
1. Always follow the instructions and warnings given by the manufacturer of any reprocessing equipment/chemicals used.
2. Instruments must be thoroughly cleaned and reprocessed prior to first use and after each subsequent re-use.
3. Instruments must be inspected prior to reprocessing for signs of any damage and/or deterioration which could compromise functionality and performance. All faulty instruments must be immediately discarded. All disassembled instruments shall be inspected for functionality after re-assembly. ***Refer also to section 15.0 (Dental Mirrors - precautionary measures/monitoring of functionality).***
4. If manually cleaning, do NOT use metal brushes, always use a soft nylon bristle brush.
5. Do NOT apply excessive pressure to the tip of the instruments as this could induce breakages.
6. For hinged instruments, check for smooth movement of the hinge without excessive play. Locking mechanisms such as ratchets must be checked for smooth action.
7. Instruments must NOT be exposed to saline and cleaning/disinfection agents containing corrosive materials.
8. Coarse impurities must be removed from the instruments immediately, do NOT allow biological soiling to dry onto contaminated instruments, as it may compromise the effectiveness of the cleaning, disinfecting and sterilising processes.
9. Ethylene Oxide (EtO), gas plasma and dry heat sterilisation are NOT recommended.
10. Use of hard water should be avoided. Softened tap water may be used for rinsing, however, purified deionised water is recommended for final rinsing to prevent mineral deposits.
11. Care and caution shall be exercised when reprocessing instruments with sharp cutting edges, delicate working points, tips and serrations.
12. Appropriate Personal Protective Equipment (PPE) shall be worn when handling contaminated/potentially contaminated instruments.

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

5.0 STORAGE (pre-use)
Instruments should be retained in their packaging and kept in a dry, clean and well-maintained environment until needed.

6.0 PREPARATION for CLEANING
Inspect instruments visually for any obvious signs of damage and/or deterioration, particular attention must be paid to cutting edges which should be free of nicks and present a smooth continuous edge. Disassemble instruments where applicable.

7.0 LIMITATIONS & RESTRICTIONS on REPROCESSING
Reprocessing in accordance with these instructions should have little effect on the functionality of the instruments. The end of life is more determined by wear and tear during use. Instruments should be inspected for defects, such as broken tips, intermittent cutting edges and compromised movement (hinged instruments) prior to and after reprocessing.

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must therefore NOT be used. Cleaning agents with a neutral pH are recommended.

8.0 PRE-TREATMENT at POINT of USE
Used instruments must be checked for any obvious signs of damage and/or deterioration, any found in a condition which causes concern, must be discarded. Remove heavy soiling with a cloth/paper wipe or a soft bristle brush. Never use abrasive cleaners or brushes with hard bristles, this may cause discolouration, pitting or corrosion. Delays in re-processing must be kept to an absolute minimum to avoid contaminants drying and making cleaning more difficult.

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

10.0 MANUAL CLEANING
In the event that manual cleaning is the only option, instruments must be cleaned in a sink specifically reserved for this purpose.

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1. Where applicable, disassemble instruments and keep joints/hinges in the open position.
2. Wearing a pair of protective gloves, carefully rinse the instruments in warm water, ideally between 30 and 40°C for at least 3 minutes.
3. Prepare a fresh bath of neutral-pH enzymatic cleaning solution following the manufacturer's instructions, soak the instruments for at least 10 minutes, making sure the instruments are completely immersed.
4. Using a soft bristle brush, thoroughly clean the instruments brushing away from the body. Special attention should be paid to instruments with cannulations, serrations, hinges and joints, these should be cleaned in both the open and closed positions.
5. Clean any grooves, inserts or holes using an appropriate brush, ensuring the full depth of the feature is reached.
6. Visually inspect features to confirm the effective removal of any debris.
7. When brushing care should be taken to avoid spreading contaminants by spraying or splashing.
8. Thoroughly rinse the instruments under warm running water (30 to 40°C) for at least 3 minutes. Ensure that the water passes through any holes, and that blind holes are repeatedly filled and emptied.
9. Immerse the instruments in a disinfectant bath adhering to the manufacturer's recommendations and instructions, ensure all instruments are sufficiently submerged. Never leave instruments sitting in disinfection solutions for extended periods of time.
10. After disinfecting, rinse the instruments thoroughly under running water or deionised water
11. Dry the instruments using a lint free cloth in a clean environment. Cannulations and cavities may be dried using compressed filter air. Never store wet/damp instruments, they must be thoroughly dry.
12. Visually inspect to ensure all contaminants/debris have been removed. Repeat cleaning steps if necessary.

11.0 AUTOMATED CLEANING

1. Use only washer disinfectors suitable for reprocessing soiled instruments.
2. Where applicable, disassemble the instrument. Instruments with joints/hinges should be kept in an open position. Instruments with cannulations and holes should be placed in such a way that they can easily drain.
3. Wearing a pair of protective gloves, load the instruments into the storage basket/hanger. Always pack heavier instruments towards the bottom, lighter instruments to the top.
4. For any heavily contaminated instruments, prior to loading rinse under running warm water for at least 2 minutes.
5. Start the programme which will take you through the following pre-programmed cycles:
   a/ flush - removes any hard to clean contaminants left over from the manual pre-clean,
   b/ wash - removes any remaining contaminants, detergents used must be specified by the manufacturer as suitable for use in washer disinfectors and for the instruments being reprocessed,
   c/ rinse - removes traces of the detergent used during the washing process,
   d/ thermal disinfection - the temperature of the load is held at the pre-set disinfection temperature for the required holding time, refer to manufacturer's recommendations,
   e/ drying - purges the load and chamber with heated air to remove residual moisture.
6. On removal from the washer disinfector, visually inspect the instruments to confirm removal of all contaminants/debris, repeat cycle if required.
7. Carefully inspect instruments for any signs of damage and/or deterioration, discard any which appear faulty.

When using an automated washer disinfector, 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.

12.0 STERILISATION

1. Wearing a pair of protective gloves, load the instruments either singularly* or in sets** into the chamber of the autoclave unit.
   *singularly - pack instruments into pouches validated for sterilisation. Ensure the pack is large enough to contain the instruments without stressing the seals.
   **in sets - load the instruments into dedicated instrument trays or general-purpose sterilisation trays. Ensure cutting edges are protected and do NOT exceed 12kg's per tray. When loading, place heavier instruments to the bottom of the tray on top of a cotton cloth or towel.
2. Store and sterilise any bow-handled instruments in a suitable holder, always leave jaws, joints and hinges in the open position.
3. Close the door of the autoclave unit and check the safety valve and pressure gauge.
4. Apply a vacuum in order to evacuate as much air as possible.
5. Admit steam at a pressure of 105kPa, when the thermometer reaches the required temperature (132 to 137°C), record the time and maintain the temperature and pressure for a minimum of 5 minutes.
6. After 5 minutes, turn off the autoclave unit and allow the instruments time to cool down before handling.
7. NOTE – when sterilising multiple instruments in one cycle, ensure that the sterilisation unit manufacturer's stated maximum load is NOT exceeded.
8. To minimise the risk of cross-contamination, avoid storing clean and soiled instruments in the same instrument tray.

The instructions from the autoclave manufacturer must be followed and adhered to at all times.

13.0 STORAGE

The instruments should be stored in the sterilisation container (pouches, dedicated instrument trays or general-purpose sterilisation trays) until required. Storage should be in dry clean conditions at ambient temperatures.

14.0 MAINTENANCE and INSPECTION

All instruments with hinged joints, metal contacts and moving parts must be lubricated with a water soluble and surgical grade lubricant after each cleaning cycle. Do NOT use any products containing silicone.

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

15.0 DENTAL MIRRORS (precautionary measures & monitoring of functionality)

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.*
2. *Prior to initial and subsequent reuse, check the condition of the mirror, in particular:*
   a/ check the integrity of the join connecting the mirror head to the shaft,
   b/ check the glass lens sits snuggly 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.

16.0 LOT NUMBER

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

17.0 DISPOSAL

Used and end of life instruments should be disposed of as clinical waste in accordance with the National regulations of the user territory.

18.0 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.

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