Re-usable Hand-Held Instruments
REPROCESSING INSTRUCTIONS

1.0 DESCRIPTION:
Perfection Plus's range of re-usable hand-held instruments are non-powered stainless steel 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.

2.0 SCOPE:
These instructions are applicable to the reprocessing of Perfection Plus's range of stainless steel 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 9.0 (Inspection & Maintenance).

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

5.0 INITIAL TREATMENT at POINT of USE:
Pre-use, instruments must be checked for any obvious signs of damage and/or deterioration, 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 heavy soiling with a cloth/paper wipe or a soft-bristle brush. 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 instruments 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 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 MANUAL CLEANING:
Whilst automated cleaning is the preferred option, if manual cleaning is the only choice, instruments must be cleaned in a sink specifically reserved for this purpose.

7.1 where applicable dissemble instruments and keep joints/hinges in the open position,

7.2 wearing a pair of protective gloves, carefully rinse the instruments in warm water for at least 3 minutes,

7.3 prepare a fresh bath of pH-neutral (6 to 10) enzymatic detergent and following the instructions provided by the supplier, soak the instruments ensuring all are fully immersed. Never leave instruments in cleaning solutions for extended periods of time,

7.4 using a soft-bristle brush thoroughly clean the instruments brushing away from the body,

7.5 clean any grooves, inserts or holes using an appropriately sized brush, ensuring the full depth of the feature is reached,

7.6 remove the instruments from the cleaning solution and thoroughly rinse under warm running water or de-ionised water for at least 3 minutes,

7.7 visually inspect the instruments to ensure all contaminants/debris has been removed, repeat steps if necessary,

7.8 dry the instruments using a lint free cloth or a dry air chamber (100°C for 2 minutes). Never store wet/damp instruments, they must be thoroughly dry,

7.9 *if using an ultrasonic cleaner, follow the recommendations of the equipment manufacturer; as per point 7.3 use a pH-neutral (6 to 10) enzymatic detergent following the instructions provided by the supplier,*

7.10 visually inspect the instruments to ensure all contaminants/debris has been removed, repeat if necessary,

8.0 AUTOMATED CLEAN/DISINFECT:
Use only CE-marked and appropriately maintained medical washer disinfectors validated as suitable for cleaning and disinfecting soiled stainless steel instruments.

8.1 where applicable disassemble instruments and keep joints/hinges in the open position. Instruments with cannulations and holes must be placed in such a way that they can easily drain,

8.2 wearing a pair of protective gloves carefully load the instruments into the storge basket/hanger. Always pack the heavier instruments towards the bottom, the lighter instruments towards the top and ensure there is no contact between the instruments,

8.3 carefully place the storage basket/hanger into the washer disinfector and start the programme following the equipment manufacturer's recommendations,

8.4 after the initial wash cycle use a pH-neutral (6 to 10) enzymatic detergent to break down any remaining adherent soiling,

8.5 for the disinfect cycle use a high level thermal disinfection solution such as Cidex OPA, which is a glutaraldehyde-free disinfectant. Disinfect at between 90 to 95°C for 1 minute,

8.6 remove the instruments from the washer disinfector and visually inspect the instruments to confirm the removal of all contaminants/debris; repeat the cycle if necessary,

8.7 carefully inspect the 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.

9.0 INSPECTION & MAINTENANCE:
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.

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.

10.0 PACKAGING:
Ensure all instruments are completely dry before packaging, then package the clean disinfected instruments immediately.
We recommend the use of Perfection Plus instrument cassettes, push-bar instrument trays and Self-Seal Sterilisation Pouches. 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.

11.1 wearing a pair of protective gloves, carefully load the instruments either singularly(i) or in sets(ii) into the chamber of the autoclave unit.

(i) carefully pack instruments into pouches validated for steam sterilisation. Ensure the pack is large enough to contain the instruments without stressing the seals.

(ii) load the instruments into dedicated instrument trays or general-purpose sterilisation trays. Ensure cutting edges are protected. When loading, place heavier instruments to the bottom of the tray on top of a cotton cloth or towel.

11.2 store and sterilise any bow-handled instruments in a suitable holder, always leave jaws, joints and hinges in the open position,

11.3 switch on the autoclave unit and when the temperature reaches 134 to 137°C, maintain for a minimum period of 3 to $3^{1/2}$ minutes,

11.4 turn off the autoclave unit and allow the instruments time to cool down before handling. Autoclaves with an automated drying programme are recommended,

11.5 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 instruments 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 instruments are reprocessed immediately. To prevent damage and/or deterioration during transportation, 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.

Re-usable Hand-Held Instruments
REPROCESSING INSTRUCTIONS

14.0 WARNINGS & PRECAUTIONS:

14.1 always follow the instructions and warnings given by the manufacturer of any reprocessing equipment/chemicals used,

14.2 instruments must be thoroughly cleaned and reprocessed prior to first use and after each subsequent re-use,

14.3 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,

14.4 if manually cleaning, do NOT use metal brushes, always use a soft nylon bristle brush,

14.5 do NOT apply excessive pressure to the tip of the instruments as this could induce breakages,

14.6 for hinged instruments, check for smooth movement of the hinge without excessive play. Locking mechanisms such as ratchets must be checked for smooth action,

14.7 instruments must NOT be exposed to saline and cleaning/disinfection agents containing corrosive materials,

14.8 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,

14.9 Ethylene Oxide (EtO), gas plasma and dry heat sterilisation are NOT recommended,

14.10 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,

14.11 care and caution shall be exercised when reprocessing instruments with sharp cutting edges, delicate working points, tips and serrations,

14.12 appropriate Personnel Protective Equipment (PPE) should be worn when handling contaminated/potentially contaminated instruments.

15.0 LIMITATIONS & RESTRICTIONS on REPROCESSING:

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

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.

16.0 DISPOSAL:

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

17.0 LOT NUMBER:

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

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.

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.

19.0 Warranty:

Perfection Plus Ltd, will replace any of their hand-held instrument range where deviations in performance resulting from proven deficiencies in the materials and/or manufacturing processes, occur within 5-years for forceps, 3-years for elevators and 2-years for all other hand and ancillary instruments, commencing from date of purchase.

This warranty is void, however, in the event that the damage caused results from the improper use, handling and storage of the instrument, and where discolouration and/or corrosion has resulted in a failure to adhere to the reprocessing instructions provided.

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

Perfection Plus Ltd
6 Westwood Court
Brunel Road
Hampshire
SO40 3WX, UK
www.perfectionplus.com

Perfection Plus EU Ltd
The Black Church
St Mary's Place.
Dublin, Ireland,
D07 P4AX
Regulatory@perfectionplus.com

EC REP
Advena Ltd
Tower Business Centre
2nd Floor Tower Street
Swatar, Malta

MD

CE