INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES

The following instructions are for all reusable medical devices shown in this catalogue, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

WARNINGS

- Follow instructions and warnings as issued by manufacturers of any decontaminents, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 140°C.
- Aluminium based products are damaged by high alkaline solutions (pH >7).
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.

Limitations on Reprocessing

- Repeated processing has minimal effect on these instruments.
- End of life is normally determined by wear and damage in use.
- Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

INSTRUCTIONS

From Point of Use

- If possible, soiled instruments should be placed in a holding solution (combined disinfectant / enzyme solution) immediately after use and prior to cleaning, avoiding the use of bleach-based solutions.

  Note: *this process is not suitable for aluminium instruments.*

Preparation for Decontamination

- Disassemble where intended by trained staff only, without the use of tools unless specifically provided by the manufacturer.
- Reprocess all instruments as soon as it is reasonably practical following use.

Cleaning: Automated

- **Use only either CE marked or validated washer-disinfector machines and cleaning agents, following the manufacturers' instructions for use, warnings and recommended cycles.***
- Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain.
- Place heavy instruments with care in the bottom of containers.
- Place instruments with concave surfaces (e.g. curettes) facing down to prevent pooling of water.

Cleaning: Manual

- **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process: -**

  One: Using a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from instrument (water temp <35°C).

  Two: Keeping the instrument submerged in the water, with a brush, apply CE marked cleaning solution to all surfaces. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body. Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions.

  Three: Rinse instruments thoroughly with clean running water, so that the water reaches all parts of the instrument, then carefully hand dry or use an industrial drying cabinet.

  Note: *when manual cleaning is used it may not be possible to disinfect the device prior to further handling.*

Cleaning: Inspection

- After cleaning, check all surfaces, cannulations, holes and lumens for complete removal of soil.
- If any soil is still visible, return the instrument for repeat decontamination.

  Note: *automated cleaning may not be suitable for all lumens and cannulae, in which case clean manually with an appropriate brush (and stilette if provided) that reaches the depth of the feature.*

Maintenance

- Apply surgical grade lubrication oil to hinges, joints and moving parts as per the lubrication oil manufacturer's instructions.

Inspection and Function Testing

- Visually inspect and check:-
  - all instruments for damage and wear
  - cutting edges are free of nicks and present a continuous edge
  - jaws and teeth align correctly
  - all articulated instruments have a smooth movement without excess play
  - locking mechanisms (such as ratchets) fasten securely and close easily
  - long, slender instruments are not distorted
  - any component parts f t and assemble correctly with mating components.
- Remove for repair or replacement any blunt, worn out, flaking fractured or damaged instruments.

  Note: *if an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilised and be accompanied with the relevant documented evidence.*

Packaging

- All instruments to be packed following local protocol, ensuring the pack is large enough to contain the instrument without stressing the seals.

Sterilisation

- **Either CE marked or validated vacuum autoclave operating at 134-137°C 2.25 bar for a minimum holding time of 3 minutes - always following the instructions of the machine manufacturer.**
- When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
- Ensure instruments are dry before sterilisation. If the instruments cannot be dried prior to sterilisation, then use distilled/de-ionised water in the final-rinse stage of cleaning.

Storage

- Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature and away from direct sunlight.

Additional Information

- Other forms of **cleaning** (ultrasonic, alkaline and neutral) and **sterilisation** (Low Temperature Steam, Formaldehyde, Ethyleneoxide and Gas Plasma) are available. However, always follow the instructions for use as issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.

*** These instructions have been validated using a washer-disinfector cycle validated to include two cold rinses at <35°C, a detergent cycle and a rinse cycle both at >50°C, a disinfection cycle operating at a temperature of between 80°C and 87°C for a minimum holding time of 1 minute and a 20 minute drying cycle. The detergent used was a low foaming, non-ionising spray wash detergent cleaner (max 12 pH) and the rinse aid a neutral pH low foaming, non-ionic surfactant with isopropyl alcohol.**

It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

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