Instructions for Re-Processing Reusable Medical Devices

Devices: instruments which require no additional information (for handling, assembly/disassembly, or processing) other than those covered by the below table in conjunction with all applicable current Australian & International Standards. Also ensure processing meets local departmental policies.

Active devices: and specialised instruments requiring additional instruction are always identified and supplied with device.

Manufacturer: INKA™ Surgical Instruments

The following instructions are provided as a guide to achieve optimal performance and longevity from your new device. Appropriate selection, use for intended purpose only, appropriate maintenance, care & handling underpin these instructions.

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<th>INKA reusable Surgical Instruments (excluding active or specialised devices)</th>
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</table>

WARNINGs

- Instruments with: Rubber (latex free), Plastic, Aluminium, black coating, Lead, Chrome, Nickel, Tufnol, Acetal (POM) : use only non-alkaline, neutral cleaning agents in combination with fully demineralised water.
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Do not exceed 140°C during any part of the process.
- Battery operated devices: remove battery prior to cleaning (use only non-leak batteries).

Fiber Optic Rods

- Shall be removed and cleaned utilising manual or automated cleaning prior to sterilisation.
- Do NOT immerse Fiber Optic Rods in water, or rinse under cold water or any other fluids.
- Allow to cool to ambient room temperature without forced cooling.

Insulated Devices: All devices are supplied having passed insulation testing. All insulated devices must be inspected prior to each re-processing to ensure insulated areas are in tact according to local regulations.

- Insulation Integrity inspection should occur prior to each re-processing – device testing (which is not an insulation integrity test) should only be carried out by the manufacturer (refer to assistance documents on our website for appropriate insulation integrity testing).
- Insulated devices can be reprocessed following standard manual or automated cleaning as described below, and steam sterilised as described below. Any other forms of sterilisation are not recommended, and are expressly excluded from this IFU.

Limitations on reprocessing

- Repeated processing has minimal effect on reusable surgical instruments.
- End of life is normally determined by wear and damage due to use.
- McKesson Mouth Props: recommended product re-use life cycle is up to 50 cycles.

INSTRUCTIONS: Surgical Instruments (excluding active or specialised devices)

.instrument which require no additional information (for handling, assembly/disassembly, or processing)

**Point of use**: Remove excess soil.

**Containment & Transportation**: No particular requirements. It is recommended that instruments are reprocessed as soon as is practical following use.

**Reprocessing agents & equipment**: It is assumed that commercially available products approved for the intended application are used and that the user complies with recommended concentrations, exposure times and temperatures. It shall be guaranteed also that no residues remain on the items. Fully demineralised water shall be used in the final rinse.

**Preparation for Cleaning**: Disassemble all instruments where required.

**Cleaning**: Automated

- Equipment: Washer/Disinfector exposure times and temperatures shall comply with ISO 15883. Cleaning agents as per validation study in recommended concentrations shall be used:
  1. Load instruments so that hinges are open and cannulations and holes can drain.
  2. Ensure cannulated instruments are attached to specific MIS basket components.
  3. Run Washer/Disinfector cycle complying with manufacturers’ recommendations.
  4. When unloading inspect instruments esp. cannulations, holes etc. for complete removal of visible soil. If soil present repeat process or use manual cleaning.

**Disinfection**: If chemical disinfectants are used ensure all manufacturers recommendations are complied with.

**Automated Disinfection**: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to Au- Value (see ISO 15883 & AS/NZS4187).
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<tr>
<th><strong>Drying</strong></th>
<th>When drying is achieved as part of a washer/disinfector cycle, do not exceed 120°C. The air used for drying must be filtered. If needed, additional manual drying can be performed with a lint free towel. Insufflate lumens of instruments by using sterile compressed air.</th>
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<td><strong>Maintenance:</strong></td>
<td>Apply a small quantity of surgical grade lubricant to hinges as required. Separate blunt or damaged instruments, where required complete repair process as per local policies Modification and or repair via third party voids all warranty rights and liability(ies)</td>
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**Inspection and Function Testing:**

| All instruments: Visually inspect for damage or wear |
| Cutting edges: should be free of nicks and present a continuous sharp edge |
| Jaws & Teeth: Ensure correct alignment |
| Hinges: check for smooth movement without excessive “play” |
| Locking (ratchet) mechanisms: checked for correct action |
| Instruments with long slender features (particularly rotating instruments): check for distortion |
| Device consisting of components: ensure all components are present and check assembly |

*Instrument(s) returned to supplier shall be decontaminated including sterilisation and returned with relevant documented evidence.*

**Packaging:**

The sterile barrier system shall conform to ISO 11607-1 and ISO 11607-2

- Ensure all instruments are dry prior to packaging
- Singly: Ensure that the pack is large enough to contain the instrument without stressing the seals
- Sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilisation trays
- Ensure that cutting edges are protected
- Do not exceed weight limits advised by steriliser manufacturer
- Wrap trays using appropriate method

**Sterilisation**

Steam sterilise instruments under consideration of respective country guidelines at:

- 134°C to 137°C @ 204kPa (2.0bar) to 230kPa (2.3bar) minimum hold time 4 minutes
- Drying time minimum 10 minutes. Ensure dryness test has been completed.
- Ensure relevant time and temperature parameters and hold times are met as identified in applicable International Standards and Steriliser Manufacturers recommendations
- HP – GP – EO – LTSF: to be used only if recommended by Steriliser Manufacturer

**Storage:**

Storage requirements as described in AS/NZS4187 shall be met

**Reprocessing validation study information**

- The following test devices, materials & machines have been used for validation study:
  - Detergent: Neodisher FA; Dr Weigert, Hamburg
  - Neutraliser: Neodisher Z; Dr Weigert, Hamburg
  - Washer/Disinfector: Miele G7736 CD
  - Instrument Rack: Miele E 327-06
  - Keyhole Surgery Rack: Miele E 450

**Additional Information:**

- When sterilising multiple instruments in one steriliser cycle ensure that the steriliser’s maximum load specification is not exceeded.
- If the described chemistry & equipment are not available, it is the duty of the user to validate process.

**Manufacturer Contact:**

See business card for local representative or Head Office 1800 756 757

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The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and qualified personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided shall be properly evaluated for effectiveness and potential adverse consequences by the user.

It is the responsibility of the purchaser who acquires this product to ensure that all instructions/precautions contained in this document are conveyed to all relevant departments and staff.

*INKA™ Surgical Instruments reserves the right to make changes without prior notice.*