

Reprocessing Instructions:

Manufacturer:	Inter-Med, Inc.
Device:	Stat-Pak™ Packers, Aspirators, Valves, Air/Water Syringe Tips, Metal Mirror Stems, Scaling Tips, Aspirating Syringes

WARNINGS

- Appropriate PPE (gloves, safety glasses, scrubs or lab coat) should be worn when reprocessing medical devices.
- Do not disassemble devices.
- Do not use abrasive cleaners.
- Use neutral pH detergents during cleaning.
- Do not use with commercial sterilization wraps or pouches with sterilization indicators that leave a stain.
- For autoclavable products, do not sterilize with other products. Do not allow products to touch one another during autoclaving.
- Reprocess products as soon as possible after use.
- It is the user's responsibility to ensure that all reprocessing equipment used is properly validated, maintained, and calibrated in accordance with equipment specification and requirements.
- Reference should be made to the device's instructions for use / user manual for additional information which may be applicable to reprocessing.

Limitations on process:

- The products should be thoroughly inspected and tested for functionality after each reprocessing cycle. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed. Operator use and care will impact how long product will last. Contact Vista Apex with any questions.
- Vista Apex has validated the following number of reprocessing cycles for the products:
 - Stat-Pak™ Packers, Aspirators & Valves, Scaling Tips, Aspirating Syringes, Air/Water Syringe Tips or Metal Mirror Stems: 80 cycles

INSTRUCTIONS**Initial treatment at the point of use:**

- Following clinical use, the product should be immediately rinsed with water and any channels should be flushed. Remove any visible debris or contamination using a lint free cloth.
- If reprocessing cannot be performed immediately, soak product in a mild, pH-neutral detergent until cleaning can be performed and maintain separation of soiled product from non-contaminated devices to avoid cross-contamination.

Preparation before cleaning:

- No disassembly is required for reprocessing. Do not attempt to disassemble product.
- Remove any visible gross debris and wipe using a lint free cloth. For non-electronic devices, water may also be used.

Cleaning & Disinfection: *Automated*

- It is recommended to use a washer-disinfector meeting the requirements of ISO 15883. Products should be positioned such that they do not make physical contact with other parts in the washer-disinfector. Use a neutral-pH based cleaning agent. There are no known constraints on pressures and temperatures.

Cleaning & Disinfection: *Manual*

- If cleaning and disinfecting the device manually, thoroughly wipe device using a single-use cloth dampened with a pH-neutral, aldehyde and alkylamine-free, alcohol-based, bactericidal, virucidal, fungicidal disinfectant solution (e.g. Alpet D2 Disinfectant or equivalent) following the manufacturer's instructions for use. Wipe device on all surfaces. Redampen cloth as needed.
- After 1-3 minutes of contact time, remove the disinfectant solution residue with a damp cloth. Use deionized water to dampen cloth.
NOTE: Any lumens, grooves, or fluid paths should be cleaned in an equivalent manner using an appropriately sized non-abrasive cleaning brush following the same steps above.

Drying:

- Dry with gauze or lint-free cloth. Air dry until liquid is no longer present (approximately 30 minutes).

Maintenance, inspection and testing:

- Thoroughly inspect and test the product for functionality after each reprocessing cycle. Confirm product is free of debris and not damaged. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed.

Packaging:

- No special packaging is required for sterilization.

Sterilization:

- Moist heat sterilize in accordance with ISO 17665-1 at 132°C or 134°C, 0.22mPa for at least 3 minutes (20 minute dry time).

Storage:

Store in a clean and dry location. Maintain separation of soiled from non-contaminated devices to avoid cross contamination.

Additional information:

No additional information needed for reprocessing.

Manufacturer contact:

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