


Manufactured by:

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IMPORTANT: PLEASE READ

Please consult the relevant surgical manual for more information.

WARNING:


Southern Medical instruments are not supplied sterile. Prior to use, reusable instruments must be thoroughly cleaned and sterilised using validated hospital methods or following the validated instructions described below.



Implants not specifically labelled as "STERILE" must be sterilised before use. Implants may not be re-sterilised or reused after coming into contact with any human tissue or bodily fluid. Discard contaminated implants.

POINT OF USE:

- Contaminated instruments should be wiped clean of visible soil at the point of use to prevent the drying of soil and contaminants in and on the item. Do not allow saline, blood, tissue, bone or other body fluids to dry on instruments.
- Keep instruments moist to prevent soil from drying by placing instruments in a basin of purified water or by covering instruments with a damp cloth.
- For best results and to prolong the life of the surgical instrument, clean immediately after use.

PREPARATION FOR CLEANING:

- Instruments capable of disassembly must be disassembled and instruments with moving parts must be fully opened prior to cleaning.
- Low pH (6.0 to 8.0) detergents must be used. Detergents with a pH level beyond this range can have an adverse effect on the material. Detergents should be prepared at the concentration and temperature recommended by the manufacturer.
- There are some alkaline detergents that have been formulated to be safe for the cleaning of medical devices. The manufacturers of these detergents can usually provide information regarding incompatible materials. Note that aluminium instruments are damaged by alkaline detergents and solutions (pH>7).
- Soaking instruments in a low pH enzymatic detergent facilitates cleaning, especially in instruments with complex features and hard-to-reach areas.
- Water quality affects cleaning. The use of hard water could lead to mineral deposits and ineffective decontamination. It is recommended to use de-ionised water for cleaning.

CLEANING: AUTOMATED

Note: Automatic washers/disinfectors should be operated according to the manufacturer's instructions.

- Instruments with complex features, hard to reach areas or any visible or dried-on soil must be pre-cleaned. Pre-clean instruments by soaking in enzymatic detergent for a minimum of five (5) minutes and gently scrubbing the instrument to remove visible soil. Particular attention must be given to joints, cannulas, crevices and other areas that are difficult to clean. Where possible, use a twisting action to clean instruments. Appropriately sized brushes and/or pipe cleaners should be used. A syringe can also be used to access hard to reach areas.
- Load the instruments in the washer such that all design features are accessible and adequately exposed to cleaning materials. Any features that could retain liquid (e.g. hinges, holes) must be oriented to facilitate drainage.
- Run the automatic wash cycle. Minimum cycle parameters:

	Phase	Function	Duration [min]
2	Rinse with cold and warm water	Rinse, mixed water	2
5	Wash with detergent at 43°C	Wash with detergent	7
13	Rinse with warm water at 45°C	Rinse, warm water	2
16	Disinfection at 91°C	Thermal disinfection	1 + heating

- Visually inspect instruments for soil under normal lighting conditions. For features that are difficult to inspect, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.
- Repeat the process until no visible debris remains.

CLEANING: MANUAL

- Completely submerge instruments and allow to soak for a minimum of ten (10) minutes in a low pH enzymatic detergent.
- Use soft bristle cleaning brushes to gently scrub instruments. Particular attention must be given to joints, cannulas, crevices and other areas that are difficult to clean. Where possible, use a twisting action to clean instruments. Appropriately sized brushes and/or pipe cleaners should be used. A syringe can also be used to access hard to reach areas.
- If components of the instrument can be disassembled, retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
- Remove instruments from detergent and rinse thoroughly with warm water. Holes and other hard to reach areas must be rinsed repeatedly.
- Visually inspect for soil under normal lighting conditions.
- Repeat the process until no visible debris remains.

DRYING:

Place instruments on a lint-free cloth and allow to air dry. Do not use any drying agents.

MAINTENANCE, INSPECTION AND TESTING OF INSTRUMENTATION:

Visually inspect instruments after cleaning and prior to use. Return any instruments that are broken, discoloured, corroded, cracked or otherwise defective to Southern Medical. Confirm the smooth operation of instruments with moving parts. Cutting edges must be continuous and free from nicks and abrasions. Do not use defective instruments.

LIMITATIONS ON REPROCESSING:

Repeated processing has a minimal effect on instrument life. End of life is normally determined by wear or damage caused by use.

PACKAGING:

Instruments must be placed inside the Southern Medical instrument tray. Implants must also be placed on trays, either in the implant caddies provided or kept in the autoclave pouches in which they are supplied. Trays must be wrapped in an FDA cleared sterilisation wrap.

STERILISATION:

Only sterilise instruments after adequate cleaning. When loading instrument trays in the autoclave, do not stack trays. Run the steam sterilisation cycle at the following cycle parameters to achieve a sterility assurance level (SAL) of 10⁻⁶: Pre-vacuum, 132°C (270°F), 3 minute exposure, 15 minute vacuum dry, steam sterilisation cycle.

STORAGE:

- Instruments that need to be stored between cleaning and sterilisation should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet storage.
- Trays can be stacked for storage purposes.

Validation testing to support these cleaning and sterilisation instructions was conducted based on recommended guidelines and standards for reusable instruments (ISO 17664 and ISO 15883). It is the responsibility of the healthcare facility to ensure that all cleaning and sterilisation equipment and materials are validated in order to achieve the desired result. Personnel responsible for the cleaning and sterilisation must be suitably qualified. If uncertain, please contact a Southern Medical representative.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING:

CONSULT THE INSTRUCTIONS FOR USE



CAUTION



CAUTION: FEDERAL LAW
RESTRICTS THIS DEVICE TO
SALE BY OR ON THE ORDER
OF A PHYSICIAN



NON-STERILE

