

STERILISATION WRAP - (S60 - Large)

INSTRUCTIONS FOR USE:

1) Sterilization Wrap has been validated to preserve sterility and prevent wet packs with intended use in the following sterilization modes and cycles when wrapping medical devices in the healthcare provider environment:

- Pre-vacuum steam cycle

4 Minutes Exposure at 270° F/132° C with the minimum dry time of 20 minutes

- Gravity steam cycle

30 Minutes Exposure at 250°F/121°C with the minimum dry time of 20 minutes

- 2) Condition wraps at ideal temperature and humidity for a minimum of two hours at Temperature between 68° F to 73° F / 20° C to 23° C and Relative Humidity between 30° to 60° .
- 3) Visually inspect Sterilization Wrap for any damage or contamination and discard if damage or contamination is detected.
- 4) Clean and dry all medical devices and/or equipment intended to be enclosed or wrapped prior to sterilization.
- 5) Do not use wrapped contents if wrap is torn, wet, or compressed.
- 6) Prior to use, assure that all medical devices intended to be sterilized while wrapped within are compatible with and sterilizable by the sterilization cycle listed.
- 7) Consult the sterilization instructions for all devices intended for sterilization. Some medical devices, regardless of the sterilization method and sterilization wrap/container used, may require special consideration in packing configurations to ensure sterilization.
- 8) Do not use it in the presence of flammable anesthesia. The wrap is non-conductive.
- If sterilization is performed by an outside contract facility, the wrapped devices should be protected from contamination by an additional covering.

Wrapping Instructions:

- 1) Place instruments on one sheet and wrap using typical aseptic wrapping technique.
- 2) Place this wrapped "package" on a second sheet and wrap again and secure the Wrapped Package:
- 3) Secure with a common closure (tape or alternate closure suitable for the sterilization method to be used) and label.
- 4) Closure must 1) allow the sterilant to penetrate the wrapped package, 2) avoid constriction of the package and 3) maintain package integrity













Manufactured and Sponsored by

Softmed Manufacturing Pty.LTD 131 National Boulevard, Campbellfied VIC 3061, Australia

ARTG NUMBER: 362613 CODE: SM-SW63L



Compliance Management

EC REP Solutions Europe
2 Bulgaria Street.,
2850 Petrich, Bulgaria



Storage Requirements Prior to Use: Store in clean, dust free, dry conditions and keep away from fluorescent or ultraviolet light. Use original packaging during storage or

PERFORMANCE TESTED TO:

EN ISO 11607-1 FN 868-2