



CONFIRMATION OF PROCESSING

Declares that the medical device described hereafter as:

The Warwick Range of Reusable Medical Holloware includes the following product groups;

Instrument Trays, Compartment Trays, Silicone Protection, Tray Tags, Disinfection Sets, Gallipots, Lotion Bowls, Theatre Bowls, and Kidney Dishes.

can be sterilized by steam autoclaving, ethylene, oxide and gas plasma processing (ASP Sterrad)

Dated 30th September 2009

Alex Green
Quality and Compliance Manager
On behalf of Warwick Sasco Ltd



27 YEARS OF EXCELLENCE



Information provided by Warwick SASCo Ltd for the processing of re-sterilizable medical devices

Product Group: Warwick Range of re-useable Medical Devices-
The Warwick Range: Instructions for processing by Washer Disinfector and Sterilizer

Warnings	Do not exceed 137°C Do not use any abrasive powders or metal brushes as these may cause scratching on surfaces
Limitations on Reprocessing	The Warwick Range is designed for repeated processing, the end of product life is normally determined by wear and tear and damage due to use
INSTRUCTIONS	
Point of Use:	Remove excess soil with disposable cloth/wipe
Containment and Transportation	It is recommended that The Warwick Range is reprocessed as soon as is practical following use. Devices should be transported in hospital containers and returned to decontamination unit.
Preparation for Cleaning	No Particular Requirements Inspect products before processing if damaged report to your Manager and withdraw product from use. Disassembly is not normally required except when an instrument strainer or lid is used.
Cleaning : Automated	Machine Cleaning is recommended in a Washer Disinfector that complies with ISO15883, HTM 2030 Products should be positioned to allow maximum drainage, they should not be inter stacked Products can be cleaned with Alkaline, Acidic and Neutral detergent. Machine can operate at maximum water temperature of 91°C For final rinse de mineralised water is recommended. The Warwick Range is designed for Washer Disinfector programmes which include, pre-wash, cleaning, neutralisation, intermediate rinse, and disinfection and drying cycles as recommended by the Washer Disinfector Manufacturer.

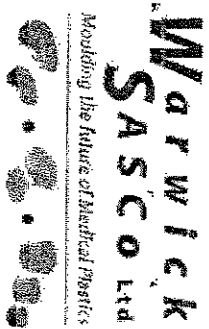
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<p>Cleaning: Manual</p>	<p>When unloading undertake a visual check to ensure complete removal of soil.</p> <p>Manual Cleaning is permissible but not recommended. Equipment: Detergent, Brush, Running Water Rinse excess soil from device Apply detergent to all surface and use brush to clean all surfaces, ensuring that mesh base and drainage holes are clean and free from soil. Rinse Dry with lint free cloth.</p>
<p>Maintenance</p>	<p>The Warwick Range does not require maintenance,</p>
<p>Inspection and Function</p>	<p>We recommend a visual inspection to assess for wear and tear and damage due to use. Discard damaged devices.</p>
<p>Packaging</p>	<p>Singly: A standard Packaging Material may be used. Ensure that the pack is large enough to contain the device without stressing seals. Pouches: We recommend choosing a pouch adapted to the size of the device and should not exceed 75% of the space inside the pouch. Wrapping: The wrap should not be too tight so as to deform the product during sterilization.</p> <p>Insets: Instruments and other medical devices may be loaded into The Warwick Range but the weight should not be too heavy to cause distortion when lifting. Trays should be wrapped by appropriate method.</p>
<p>Sterilisation</p>	<p>It is recommended that The Warwick Range is sterilised in moist heat hospital autoclaves compliant to HTM2010, BS3970, and EN285:1996 and ISO17665. Other permissible forms of sterilisation include:- Ethylene Oxide and Plasma Gas Processing. Please refer to the machine manufacturers processing information (manual).</p>

**COMPLIANCE TO BS EN ISO 17664:2004
 STERILISATION OF MEDICAL DEVICES**

Information provided by Warwick SASCO Ltd for the processing of resterilizable medical devices

	<p>Liquid Steriliants Do not exceed 137°C</p>
<p>Storage</p>	<p>Unprocessed products must be stored in a primary polythene bag. Second level of packing is advisable ie: cardboard box. Products are to be stored in dry conditions off the floor Products are to be stored above a minimum temperature of 4°C</p>
<p>Manufacturer Contact</p>	<p>Decontaminated Devices are to be stored according to Hospital Protocol in a clean dry area on secure racks. Warwick Sasco Ltd, Warwick House, Heathcote Way, Warwick, CV34 6TE Tel: 0044 (0) 1926 422427 Fax: 0044 (0) 1926 351405 info@sasco.co.uk</p>
<p>Additional Information</p>	<p>The information provided by Warwick SASCO are recommendations for 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 trained 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 should be properly evaluated for effectiveness and potential adverse consequences.</p> <p>The Warwick Range of Products conform to :</p> <p>ISO9001:2008 EEC Directive 93/42 ISO13485:2003 Other Referenced Standards: HTM2030, ISO15883:2006, BS5452:1997, BS EN980:2003, BS EN ISO14971:2007 BS2745 1977. MB2318 Maximum temperature 90°C Do not Autoclave Caution.</p>



**COMPLIANCE TO BS EN ISO 17664:2004
STERILISATION OF MEDICAL DEVICES**

Information provided by Warwick SASCO Ltd for the processing of resterilizable medical devices

Steel instruments take longer to release heat. To prevent distortion thin wall, light-weight plastic products must be positioned from steel instruments.