






GENERAL INSTRUCTIONS & RECOMMENDATIONS FOR THE USE, CARE AND MAINTENANCE OF BLACKENED SURGICAL INSTRUMENTS		MDL 062n rev 5 24/02/2025
		
INTENDED USE:	Blackened surgical instruments supplied by Bolton Surgical Ltd are re-usable devices intended for use in surgical procedures where surface light reflectivity must be minimised.	
HOW SUPPLIED:	Bolton Surgical Blackened Instruments are supplied non-sterile and must be cleaned and sterilised before each use according to the instructions and recommendations outlined below.	
	<b>WARNING: If this device is/was used on a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilise without cross-contamination risk.</b> <b>WARNING: Avoid using chemical cleaners as they can cause severe damage to the blackened surface.</b>	
INSTRUCTIONS & RECOMMENDATIONS		
Point of use:	<ul style="list-style-type: none"><li>• All surgical instruments must be used only by appropriately qualified surgical practitioners.</li><li>• We recommend immediate rinsing of all instruments after use to prevent biological residues becoming encrusted.</li></ul>	
Pre-Cleaning:	<ul style="list-style-type: none"><li>• Keep instruments moist and do not allow blood and/or bodily fluids to dry on them. If necessary, consider covering the instruments with a damp cloth to avoid drying out of the soil.</li><li>• Do not leave blackened instruments soaking in saline or chlorinated solutions to avoid damage to the blackened surface.</li><li>• Avoid damage to instruments during transportation for reprocessing (e.g. do not mix heavy devices with delicate items). Transport for reprocessing as soon as possible after use.</li></ul>	
Cleaning:	<ul style="list-style-type: none"><li>• <b>Blackened instruments should be kept apart from other instruments during cleaning to minimise the risk of abrasion damage to the blackened surface.</b></li><li>• <b>Only neutral pH (between 6 &amp; 9 Ph) cleaning solutions are recommended for blackened surfaces.</b></li><li>• Remove gross contaminants with a steady stream of lukewarm/cool water (below 43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.</li><li>• Where necessary, remove blood and general grime by washing the instrument in water and a <b>neutral (between 6 &amp; 9 Ph) detergent</b>. Manual or automated cleaning methods can be used although whenever possible, automated cleaning is recommended to provide greater process reliability and repeatability as well as reducing risks associated with staff exposure to contaminated devices and cleaning agents used.</li><li>• Whichever cleaning method is used, suitable protective clothing and equipment (PPE) should be worn at all times.</li><li>• Care must be taken to ensure cleaning agents are used in accordance with the manufacturer's instructions.</li><li>• To minimise abrasion damage to blackened surfaces, use only soft (non-metallic) brushes or non-abrasive scouring pads. Do not use steel wool, wire brushes, or abrasive detergents.</li><li>• Rinse in running water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the steps above if necessary</li><li>• Allow to drain on absorbent wipes or transfer immediately to inspection step</li></ul>	
Disinfection:	<ul style="list-style-type: none"><li>• Chemical Soaking must not be applied as this will reduce the life of the blackened surface.</li><li>• Blackened instruments can be thermally disinfected in accordance with the A<sub>0</sub> requirements of BS EN ISO 15883-1. The following minimum temperature/time combinations are therefore recommended: 70°C - 75°C for 100 minutes, 80°C - 85°C for 10 minutes or, 90°C - 95°C for 1 minute.</li></ul>	
Drying:	<ul style="list-style-type: none"><li>• Care must be taken to ensure that the instrument is dried thoroughly before storage. When drying is achieved as part of a washer disinfectant cycle, do not exceed 127°C.</li></ul>	
Service Life, Inspection & Maintenance	<ul style="list-style-type: none"><li>• Before each use, inspect for any damage. If the instrument is nicked, cracked or severely corroded it must be replaced.</li><li>• Damaged or defective instruments should not be used. For replacement, contact your Bolton Surgical Sales Consultant (or your local agent if outside the UK).</li><li>• Blackened instruments are re-usable but do have service life limitations due to the natural effects of wear and tear and gradual deterioration of the blackened surface with repeated use and reprocessing. Replacement is recommended therefore at the first signs of unacceptable functionality loss. As such, blackened surfaces are excluded from our standard terms of guarantee.</li><li>• In some cases blackened surfaces can be economically re-blackened. If they are returned to Bolton Surgical for inspection/repair/replacement, a certificate of decontamination must be supplied. Failure to supply evidence of decontamination will result in the products being returned untouched for reprocessing.</li></ul>	
Sterilisation:	<ul style="list-style-type: none"><li>• To minimise the risk of surface and/or mechanical damage during processing, it is recommended that <b>instruments with blackened surfaces should be kept apart from other instruments during sterilisation.</b></li><li>• <b>STEAM AUTOCLAVING is recommended:</b> Blackened instruments should be sterilised in accordance with HTM01-01 at 134°C - 137°C for a minimum of three minutes.</li><li>• <b>Note:</b> Sterilisation times are for exposure and do not include ramp up times or drying cycle times needed. Follow the manufacturer's instructions for loading and operation of steam autoclaves.</li><li>• <b>CHEMICAL STERILISATION: Should not be used</b> as this can result in severe corrosion or removal of the blackened surface.</li><li>• <b>Note:</b> The responsibility for validation of sterilisation techniques and equipment lies with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilisation chambers, wrapping methods and/or load configurations.</li></ul>	
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