HYGIENE INSTRUCTIONS FOR THE FLUTTER

Introduction

Due to the design and materials used to make the flutter it is a very hardy device, capable of being decontaminated in several ways. Laboratory testing has proved that cleaning with enzymatic detergent alone will reduce the bio-burden to an acceptable level. If greater assurance of the inactivation of pathogens is required then either liquids or moist heat can be used.

For single patient use

See the instruction in the users manual.

For multi-patient use

Method One

1. Disassemble the unit by detaching the top and tipping out the ball and cone.
2. Fully immerse the parts in an enzymatic cleaner such as Lancerzyme® in a clean sink and wash using only a soft cloth or cleaning pad to remove any deposits.
3. Rinse in deionised or distilled water a minimum of 3 times.
4. Reassemble and place in a clean container.

Method Two

1. Disassemble the unit by detaching the top and tipping out the ball and cone.
2. Place all parts in a suitable basket and wash in an automatic dishwasher on a cycle that has the following key elements
   a. Two minute pre-wash
   b. 3 minute detergent wash at 93Deg C (for example Lancerzyme®)
   c. Rinse cycle
   d. A drying stage sufficient to ensure the parts are completely dry.
3. Reassemble and place in a clean container.

Method 3

Following either cleaning method one or method two up to the last point, the parts can then be transferred to an autoclave and sterilised at 137°C and placed in a sterile container.

Method 4

Again after cleaning as described in methods one and two the parts of the flutter can be submerged in a disinfectant solution in the following way, for a period of time before being rinsed and dried.
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disassemble the Flutter, inspect for signs of damage or wear, if any is evident replace.</td>
</tr>
<tr>
<td>2</td>
<td>Prepare a solution of detergent in accordance with the manufacturer instructions in a container large enough to totally submerge the components.</td>
</tr>
<tr>
<td>3</td>
<td>Wash using only a soft cloth or cleaning pad to remove any mucus deposits. Leave in solution for recommend time.</td>
</tr>
<tr>
<td>4</td>
<td>Rinse and dry as recommended. Rinse as recommended.</td>
</tr>
<tr>
<td>5</td>
<td>Pour a quantity of the chosen disinfectant into suitable container.</td>
</tr>
<tr>
<td>6</td>
<td>Immerse and agitate to ensure air is expelled and leave it in the solution for the recommended time. Leave in solution for recommend time.</td>
</tr>
<tr>
<td>7</td>
<td>Rinse as stated, shake gently to remove any excess water and allow to dry naturally, do not use hot air or a drying cupboard. Dry naturally and reassemble.</td>
</tr>
</tbody>
</table>
## Disinfectants

The following disinfectants have been tested for compatibility with the Flutter at the stated concentrations only.

<table>
<thead>
<tr>
<th>Chemical type</th>
<th>Examples</th>
<th>Solution strength</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine dioxide generator</td>
<td>Tristel one day</td>
<td>20ml in 1 litre of water</td>
<td>Safety data sheet and further information available from <a href="http://www.tristel.com">www.tristel.com</a></td>
</tr>
<tr>
<td>Sodium hypochlorite (NaOCl)</td>
<td>Milton,</td>
<td>1000 ppm</td>
<td>Ensure thorough rinsing, as corrosion of the metal parts will occur if exposed to chlorine for long periods.</td>
</tr>
<tr>
<td>Sodium dichloroisocyanurate (NaDCC)</td>
<td>Presept, Actichlor Sanichlor, Haz-Tab</td>
<td>1000 ppm</td>
<td>Follow instructions provided by the manufacturer.</td>
</tr>
</tbody>
</table>

- Clement Clarke Int. Ltd accepts no liability for damage caused to products if the above procedure and recommended solutions are not used.
- It is the user's responsibility to choose which of the recommended solutions are used within their establishment or hospital and we stress that the infection control nurse/department should be consulted when making the choice.
- It is the responsibility of the user to keep themselves current with the latest information from the relevant disinfectant manufacturer concerning instructions, effects, concentrations, and immersion times.

References: Chemical disinfection in hospitals – PHLS,
Sterilization, disinfection and cleaning of medical device equipment (MAC Manual) – MHRA

### Note

1. This method of cleaning has been independently tested and validated to ensure that if followed the flutter will be sufficiently clean for re-use.

2. Lancerzyme® is a registered trade mark of Lancer UK Ltd (www.lancer.co.uk)

3. The amount of time the device is left in the solution will depend on the disinfectant chosen.

4. The ball in the Flutter is chrome plated mild steel and in tests damaged balls have shown signs of discolouration around scratches after prolonged periods of time in a solution of Milton Fluid.

The Flutter cannot be sterilized with ethylene oxide or hot air.

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