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Reprocessing guide according to EN ISO 17664

Cleaning and Disinfecting of reusable NIV masks

NOTE This is only a copy of the reprocessing guide of VBM Medical. For the latest version or further questions contact VBM Medical directly www.vbm-medical.de

Prior to first use as well as after each use disassemble the face mask, and then submit it to reprocessing as follows:

(Dis-)Assembly

Remove the inflatable cushion from the dome. After each reprocessing assemble the cushion.

General

Please note that the products must not be in contact with hard or sharp edged objects. Silicone material must not be in contact with silicone oils and fats. The product lifetime of reprocessed products, depend importantly on a careful cleaning and disinfection. Please note that each reprocessing accelerates the natural ageing of the material and reduces the lifetime of the product. Therefore reprocessing of the products is limited. During preparation strictly follow the warnings mentioned below.

Warning

After each reprocessing or before each use the facemasks need to be checked carefully for damages (cracks, tears, etc) and tightness of the cushion. Inflate the cushion with a syringe. Deflate the cushion by opening the plug. Damaged or leaking facemasks must not be reused! To prevent penetration of fluids into the cushion, make sure to close the plug during cleaning and disinfection. During sterilization, the plug of the cushion must be open.

Cleaning

For mechanical cleaning VBM recommends pH-neutral agents. Soap solutions or alkaline agents can also be used if a citric acid-based neutralization agent is used afterwards. Abrasives, hard brushes or other materials which might damage the surface must not be used. Eliminate all residues of the cleaning agents by thoroughly rinsing with deionized water.

Disinfection

For disinfection use commercially available disinfectants for instruments which have been tested and approved for silicone or thermostable plastic materials. Disinfectants containing compounds similar to phenol or alkylamines (such as Glucoprotamin) are not suitable and may result in hardening of the material. Strictly adhere to the immersion time and application concentration recommended by the manufacturer. Eliminate all residues of the cleaning agents by thoroughly rinsing with deionised water. For disinfection VBM recommend thermal disinfection (93°C/10 min.). To prevent material-dependent ageing, the temperature for drying should not exceed 95°C.

Sterilisation

For sterilization VBM recommend a validated steam sterilization process according to DIN EN ISO 17665-1 at 132/134°C / 270/273°F (5-18 min.). Prior to sterilization the devices must be cleaned, rinsed with water and dried. Residues of the cleaning agents and disinfectants could cause damage to the material. If used correctly, the product can be reprocessed max. 100 times, respectively it has a shelf life of 5 years.

With kind regards

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