Significance of Cleanliness of Medical Devices

M Rasori

Amsonic AG, Biel, Switzerland

INTRODUCTION: Medical components cleaning (implants, instruments, etc.) is often regarded as a necessary evil in industry and is often added on at the end of the existing production lines, without any attempt to look at the production process as a whole and integrate cleaning operation in that process. The technical cleanliness of components, their functional surfaces and the production environment are absolutely essential, however, for the manufacture of high-quality medical products.

METHODS: The choice of the cleaning technique has become more complex for various reasons. Various legal requirements require a drastic change of the cleaning methods. The demand for higher cleanliness of parts is growing. The problem the medical sector is confronted with, consists in an absolute necessity for clean surfaces which are not only free of polar (e.g. salts) but also of non-polar (e.g. oils) soilings.

The use of detergents is limited due to the fact that they will be rapidly saturated by cutting oils, thus reducing their cleaning power. Oil separators and the automatically metered addition of detergent components however, improve their efficiency. Degreasing in open tanks of chlorinated solvents was a simple and efficient way to clean parts. But it was also highly polluting the environment and toxic for the operators. This method has been replaced by fully encapsulated machines using non chlorinated AIII hydrocarbon solvents under vacuum.

Nowadays, preliminary and intermediate cleaning systems in the field of medical technology are often based on AIII solvent cleaning. AIII solvents are hydrocarbons, either modified alcohols or isoparaffins, with a flash point of between 56 and 100°C. They are extremely stable where their storage life is concerned, leave a protective film that is approximately 2 to 13 nanometers thick and can be recycled using vacuum distillation. This system enables the fully automatic cleaning, steam degreasing and drying of components. Cleaning quality is further enhanced by ultrasound and microfiltration.

In order to be able to guarantee the required level of biocompatibility, the final cleaning process is carried out using water-based ultrasound immersion cleaning systems. Here, the water-based cleaning complies with a series of complex requirements, such as

- Intensive, yet gentle cleaning of various materials.
- Complete removal of various impurities, e.g. swarf, polishing agent residues, grinding residues, salts or minerals.
- Activation or passivation of material surfaces and their preparation for all types of subsequent processing.

Fig 1: Amsonic Cleaning unit, Amsonic 4000

RESULTS: Thanks to state-of-the-art cleaning systems, user-friendly controls and extensive know-how in the field of validation and qualification support (IQ, OQ); Amsonic is able to provide the optimal prerequisites for high quality, optimised cleaning solutions.

Fig 2: Part prior to cleaning / Part after the cleaning process.

DISCUSSION & CONCLUSIONS: Owing to the fact that system components are becoming smaller and smaller and technically more complex, the expense involved in cleaning processes is rising steadily. Meeting the today growing cleanliness demands in medical industry by using a cleaning machine as an "end of pipe" solution at the end of a production process is, at more than arguable.

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Tel. +41 31 335 6 223
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