

# Amsonic AG - Traceable and reproducible cleaning technologies

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**INTRODUCTION:** Medical components' cleaning (implants, instruments, etc.) is often regarded as a necessary evil in industry and are 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 cleanness of components, their functional surfaces and the production environment is 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 its cleaning power. Oil separators and the automatic metered addition of detergent components however, improve its 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 This method has been replaced by fully encapsulated machines using non chlorinated A3 hydrocarbon solvents under vacuum.

Nowadays, preliminary and intermediate cleaning systems in the field of medical technology are often based on A3 solvent cleaning. A3 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.

**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.

**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.

Residual dirt on components not only affects the functionality of technical systems but also increases the volume of rejected samples.

Meeting the today growing cleanness demands in medical industry by using a cleaning machine as a "end of pipe" solution at the end of a production process is, at more than arguable.