Technical Article

UCMSmartLine - modular multi-chamber immersion cleaning system for validated cleaning processes in the medical industry

Intermediate and final cleaning process for knee implants in compliance with FDA and MDR regulations

MDR and the FDA have imposed regulations and requirements governing product safety, process validation and quality management on the medical device sector that are stricter than in almost any other industry. This also affects cleaning processes for parts and components. To meet regulatory challenges, an international manufacturer of knee implants has replaced its intermediate and final cleaning equipment with the UCMSmartLine. The ultrasonic multi-chamber immersion cleaning system, which is based on standardized modules, can be individually configured for specific tasks, and enables validated cleaning and passivation processes to be seamlessly monitored and documented.

With the introduction of the European Medical Device Regulation (MDR), the requirements for cleaning medical devices such as implants, as well as for validating, documenting and tracing the respective processes, have become much more stringent. However, the US Food & Drug Administration (FDA) is planning to harmonize its quality system regulations with the MDR. This will make it easier for medical device companies to comply with requirements in the future - regardless of whether they manufacture their products in the USA or Europe or export them there.
The exacting regulations imposed by the MDR require manufacturers and suppliers of parts and components to adapt their cleaning and passivation processes. This was also the case with a global manufacturer of titanium knee implants. A key stipulation made by the company was that the new equipment for intermediate and final cleaning should be easy to validate, and that the parameters of the validated processes should be consistently monitored and documented. In addition, the equipment and processes had to be easy to duplicate for sites in other countries.

One type of system for both applications

After conducting market research, the company opted for the UCMSmartLine system for both tasks. The system is made by the Swiss company UCM AG, the division of the SBS Ecoclean Group that specializes in ultra-fine and precision cleaning. The decisive factor was the concept of the ultrasonic multi-chamber immersion cleaning system, which is based on standardized modules for cleaning, passivation, rinsing and drying as well as loading and unloading. The goods are transported by an integrated automated system, complete with servo drive, that comes as standard. The electrical and control technology is integrated into

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each unit so extra space for a control cabinet is no longer needed. Thanks to the flexible and cost-efficient plug-and-play design, the systems can be individually configured for pre-cleaning, intermediate cleaning and final cleaning applications with the highest cleanliness requirements. Equipped with modern sensor technology and additional methods for measuring parameters such as pH, conductivity, density, ultrasonic frequency and output, all relevant process parameters can be seamlessly recorded, controlled and documented. The data is transmitted to the company's higher-level Manufacturing Executive System (MES) via an interface integrated into the UCMSmartLine's PC-based controller.

Task-specific configuration ensures reliable intermediate cleaning

For batch-by-batch intermediate cleaning of the knee implants, in which residues from grinding or polishing processes are removed, the fully enclosed system has a total of six wet stations with tanks measuring 370 x 420 x 390 mm (L x W x H). During the two cleaning and four rinsing cycles, multi-frequency ultrasound with 25 and 40 kHz is used in addition to injection flood washing and pulsed pressure cleaning (PPC). The two-sided overflow developed by UCM, which comes as standard, also contributes to the consistently good cleaning result: media are introduced from below, transported to the top and then overflow on two sides. This creates a constant flow that not only promotes intensive treatment of the parts but also makes sure that detached particles and other residues are immediately removed from the baths, thus minimizing the risk of parts becoming recontaminated when they are moved or lifted out. After the drying step in the integrated vacuum dryer, the implants are subjected to a full visual inspection.

Final cleaning with monitored ultrasonic frequency and output

The UCMSmartLine configured for final cleaning has seven wet stations. A cleaning and rinsing step is followed by passivation, during which the quality of the medium is monitored by measuring its density. After subsequent neutralization, the parts are subjected to three rinsing steps with corresponding water qualities. The cleaning and rinsing effect is also reinforced by injection flood washing, PPC and ultrasound with a frequency of 40 kHz during final cleaning. The newly developed Acoustic Performance Measurement (APM) system, on the other hand, provides in-line monitoring of the parameters of ultrasonic frequency and output at each processing station for each batch. Special directional microphones are used for monitoring, which are placed in a fixed position at the edge of each tank and directed towards the center of the bath surface. Thus, measurements are carried out without any movement or contact, ensuring reproducible results and enabling them to be precisely assigned to the batch concerned. Analysis, evaluation, and storage of the data are handled by the software of the innovative measuring system. Thanks to the special lift-out function of the transport system, the parts are effectively pre-dried following the last rinse before being transferred to the vacuum dryer for the final drying step, which dries the parts completely and ensures a spotless finish. At the outfeed section, the system is connected to the cleanroom by a double airlock. Due to consistent monitoring of the process parameters and the continuous comparison with validated process data means, bad baskets', in which discrepancies have been detected, can be removed from the product flow before reaching the cleanroom.

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Due to the highly flexible design of the system and processes, the UCMSmartLine is suitable for a wide range of applications, not only in the medical industry. At the same time, the standardized modules simplify equipment certification and process validation and make it easier to duplicate the cleaning systems and processes for further sites.

The system concept, which is based on standardized modules, enables the ultrasonic immersion cleaning systems to be individually configured for intermediate and final cleaning applications - also with direct connection to a cleanroom.

After final cleaning, the parts are discharged into the cleanroom. Consistent monitoring and the comparison of process parameters with validated values ensure that 'bad baskets' are eliminated before they reach the cleanroom.

The standard two-sided overflow creates an uninterrupted flow that enhances the intensive treatment of the parts. It also guarantees that cleaned-off contaminants are immediately discharged from the treatment tanks.

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Thanks to the newly developed Acoustic Performance Measurement (APM) system, the ultrasound frequency and output can be monitored and documented in-line at each processing station for each batch.

The modular final cleaning system has seven wet stations for cleaning, passivation, neutralization, and rinsing, as well as a vacuum dryer.

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About SBS Ecoclean

The SBS Ecoclean Group develops, produces, and markets forward-looking machinery, systems and services for applications involving industrial parts cleaning and degreasing, ultrasonic precision parts cleaning, high-pressure water jet deburring, surface preparation and surface treatment. Its globally leading solutions help companies around the world in conducting efficient and sustainable manufacturing to high quality standards. The client base comes from a broad range of market sectors like the industrial mass and precision manufacturing, the automotive industry with its suppliers, the aircraft & aerospace industry, medical technology and medical device, optics, and the high-tech and high purity sector. The Group's success is based on innovation, cutting-edge technology, sustainability, closeness to the customer, diversity, and respect. The Group employs a workforce of around 900 at its 12 sites in nine countries worldwide.

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