



Parts Cleaning. Systems and Solutions.



Gebrüder Zepf Medizintechnik
GmbH & Co. KG:
Clean surgical instruments
without leaving residues



User report

Clean surgical instruments without leaving residues

The requirements for cleanliness in the field of medical engineering are increasing constantly. In order to be able to clean the stainless-steel components for surgical instruments economically and, above all, reliably in future, in accordance with the high requirements of its customers, Gebrüder Zepf Medizintechnik GmbH & Co. KG relies on MAFAC's cleaning technology.

“Our goal is it to create safe and high-quality products. On our way to this point, we need surfaces, which are absolutely free from stains between the production steps as well as after production stop. Drying plays an important role in this,” explains Markus Lutter, Head of Workshop and Production. Until the procurement of the spray-flood cleaning machine MAFAC JAVA, his colleagues had to clean the surgical elements in various small tanks, which was followed by a manual drying process with an air gun. “Because of the high personnel requirements and the increasing quantities, this had not been profitable for some time. When, together with our coater, we discovered during tests that better pre-cleaning of the stainless-steel components in our company leads to direct improvements in the coating, it was time to act,” explains Authorised Representative Markus Lippoth. It was decided to reorganise the cleaning process. It was important to set up a compact and easy-to-operate process that can be used flexibly for the wide range of parts and leads to a high-quality cleaning result. “We want to continue to fully meet our quality standards in the future,” says junior manager Tobias Zepf.

Highest possible quality for surgery

This claim has been the driving force behind Gebrüder Zepf Medizintechnik GmbH & Co. KG, which was founded in 1949 in Dürbheim, in the heart of the “world centre of medical technology Tuttlingen”. The family business is now run by the second generation and employs 65 people. Thanks to a high level of vertical integration and precision work, the company ranks as a premium supplier of surgical instruments for bone and spinal surgery and serves customers from the USA, Germany and Europe, Japan and Australia. The range includes Kerrison bone punches, rongeurs, forceps, curettes and endoscopic sheaths that lead the market in cutting ability and durability. “Our strength is the combination of traditional craftsmanship with the state-of-the-art production methods. This enables us to implement individual customer wishes in terms of haptics, appearance, length, cutting width and design without minimum order quantities, and in doing so we achieve a high variety of variants with consistently high quality,” Markus Lippoth explains.

The focus will remain on the high-price segment served so far, which brings new challenges in view of the Medical Device Regulation (MDR) that has been in force since 2020. “Cleaning plays an essential role here. There are demands for cleanliness that did not exist in the past,” reports Tobias Zepf.



Gebrüder Zepf Medizintechnik GmbH & Co. KG offers a wide range of surgical instruments for bone and spinal surgery that are market leaders in cutting ability and durability.

Source of the images: Gebrüder Zepf Medizintechnik GmbH & Co. KG



The premium manufacturer is known for its wide range of variants in terms of haptics, appearance, length, cutting width and design. Models that are additionally coated and equipped with silicone handles have high cleanliness requirements.

Source of the images: Gebrüder Zepf Medizintechnik GmbH & Co. KG

Stain-free surfaces as a mark of quality for the products

On the way from the stainless-steel blank to the finished surgical instrument, the components go through a complex manufacturing process with turning, milling, welding and hardening. After hardening, the surfaces are finished by grinding, polishing and matting to achieve the desired quality. "Before the parts go on to coating or the handles are coated with silicone, we prepare them for further processing by means of intermediate cleaning," Markus Lutter explains. Intermediate cleaning is thus a crucial step, especially for coating, as the surfaces require a high level of particulate and filmic-chemical cleanliness and must not show any residues or contamination such as latent fingerprints or water marks. Therefore, machining residues such as oils, dusts and emulsions as well as hand sweat and tallow must be removed.

Before the finished instruments leave the factory, they are given a final cleaning and quality control. In the process, laboratory requirements regarding cytotoxicity and the Medical Device Regulation have to be fulfilled for the customers who act as distributors. The latter specifies risk class I_r for reprocessible surgical instruments and requires cleaning and reprocessing validation as well as proof of monitoring and control of the production processes.

Reproducible cleaning results

These requirements can be comprehensively fulfilled with the newly set-up cleaning process using the MAFAC JAVA spray-flood cleaning machine. The decisive factors for its acquisition were the process technologies developed by MAFAC of co- and counter-rotating spray and basket receptacle systems and vacuum drying as well as the machine's single-chamber system. "It was important for us that all processes are compactly combined in one machine and run reliably. We can accommodate the entire cleaning process in the production run in a space-saving manner and react flexibly to changes," explains Tobias Zepf.

The MAFAC JAVA is used for both intermediate and final cleaning. Here, spray and flooding processes ensure high turbulence, which in combination with temperature, cleaning chemistry and time, results in safe and effective cleaning of the component surfaces. Due to the pressures of the spray cleaning and the rotary movement, the workpieces are fixed as set goods in the workpiece carrier.

A total of three programmes are stored in the installed JAVA, whose running time averages 20 minutes. „In our case, cleaning is less about time than about thoroughness,“ says Markus Lippoth. During cleaning, the two baths are used in the order of cleaning and rinsing. The cleaning process takes place in two

phases: Phase 1, the actual cleaning with media tank 1 and cleaning additive. This is followed by phase 2, the rinsing process, with holding tank 2 and clear water. During the cleaning phase, the processes of spraying, flooding and spraying alternate. During this process, all dirt particles are dissolved and safely removed by flooding. The first cleaning phase is completed after a pulse blowing and lifting process, which prevents the media from being carried over into tank 2. Phase 2 then starts with a spraying process in medium tank 2. This additional rinsing process is very important for coating as it completely removes the cleaning agent residues and ensures adhesability.

Complete drying for coating

The subsequent drying is also important for the subsequent processing steps and transport to the customer. "The stainless-steel components must be absolutely dry not only because of the coating or silicone spraying, but also to avoid discolouration," Markus Lutter explains. Therefore, the decision was made to use hot-air impulse drying in combination with vacuum drying. First, the cleaned workpieces are blown off in pulses with high-purity compressed air via a rotating blowing system. This is followed by the application of ultra-fine filtered hot air - also in rotation. Then the vacuum drying system is activated, which uses negative pressure in the cleaning cell to ensure that even

recesses, narrow bores or hidden passages are absolutely dry and no water residues remain. "For us, the vacuum process is an additional security that neither moisture can bloom nor water marks can form," says Markus Lutter.

Process with many possibilities

An important aspect for which the various test cleanings and process optimisations have paid off, as Markus Lippoth finds: "I am excited about how adaptable the MAFAC machines are and how versatile aqueous parts cleaning is." This was demonstrated during the process optimisation carried out by MAFAC application engineers after the initial commissioning. "Like no other process, aqueous parts cleaning offers a wealth of parameters with which the cleaning process can be individually adjusted to the requirement in a process-safe manner. The user gains considerable flexibility, especially when dealing with different component materials or a change in component type and geometry," explains Thomas Gutman, Head of Customer Support at MAFAC. In the case of Gebrüder Zepf, it was the choice of the right cleaner and the perfect combination of the individual process steps that ultimately led to success. "With the MAFAC JAVA, we feel well positioned for the future, as we can meet the increasing demands in the long term and with process reliability," is Markus Lippoth's summary.

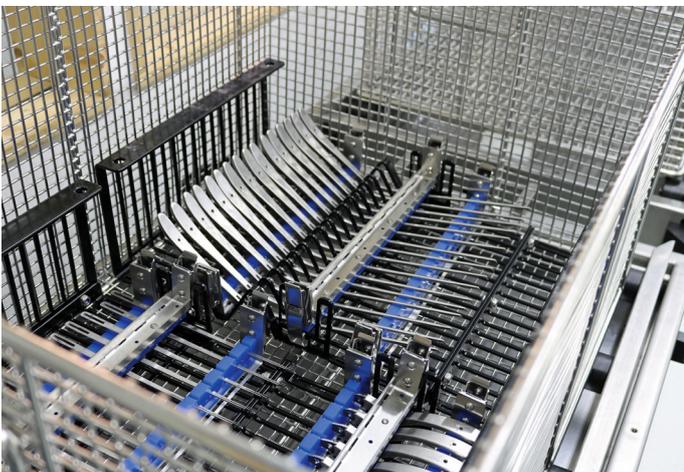


For cleaning, the stainless-steel components are fixed in a workpiece carrier as set goods and assembled into a finished instrument after cleaning. Depending on the model, they have filigree to complex geometries.



Subsequent processes such as coating and bonding with silicone require absolutely residue-free and dry surfaces. Machining residues such as oils, dusts and emulsions as well as hand sweat and tallow are removed.

After the cleaning and drying process, the particulate and filmic-chemical soiling is reliably and reproducibly removed.



The placed parts are combined into a cleaning batch and fed into the treatment chamber.



Three programmes are installed on the MAFAC JAVA. The machine is used for intermediate and final cleaning.



Thanks to its compact design, the MAFAC JAVA fits into the production run at Gebrüder Zepf. It combines all the necessary processes in one machine.



The MAFAC JAVA spray-flood cleaning machine with two-bath technology replaces cascaded cleaning tanks that were previously used to clean and dry the stainless-steel components.

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