

#### Modular system for cleaning and passivation

#### Ultrasonic cleaning of precision instruments

**A special cleaning and passivation concept has been integrated in the production process for a manufacturer of medical precision instruments. The high quality requirements can be fulfilled due to the modular design and the individually adapted cleaning process.**

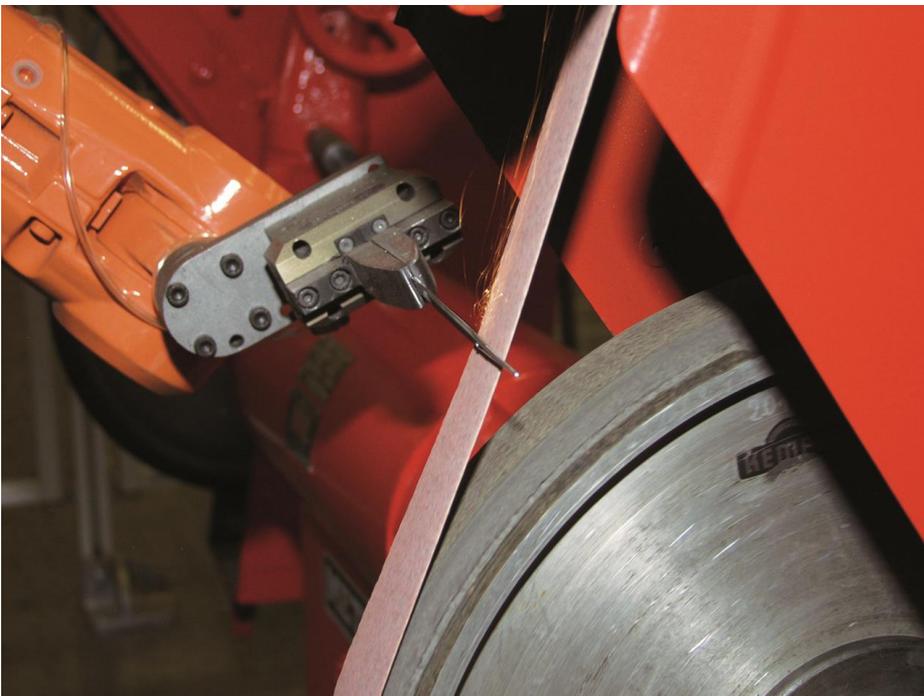
The company Allgaier Instrumente manufactures precision instruments for the medical technology sector. With approx. 26,000 products, the number of variants and the product range of the company is very wide. Particularly for the surgical area, the range includes parts which must comply with very high quality requirements. The instruments are produced using modern technology and not least in skilled manual work in numerous production steps. They are used in various fields of surgery (for example for visceral (abdominal), heart, thorax or cardiovascular operations, in orthopaedics, traumatology, urology, gynaecology or in the ENT area).

"The surgical instruments must be traceable over many years. This can also mean that an OP set and/or an individual instrument will be marked if necessary to be able to assign this to the respective OP patient data. Even more important are the quality requirements. Each instrument showing defects or that must be repaired requires further effort for documentation without gaps. Functional weaknesses are detected quickly and without gaps and do not cost unnecessary resources for the hospitals which must operate cost-effectively.

In addition to the general surgical instruments, the product range also includes parts in the minimally invasive area (so-called keyhole surgery), for example for laparoscopy, gynaecology, urology, arthroscopy, ENT to the complete OP tower.



**Interior view of the ultrasonic cleaning system for treatment of medical precision instruments.**



Robot in the manufacturing

### Processes that can be validated

The ISO 9001/ EN 46001 (currently ISO 13485) quality management system established since 1995 is implemented daily. The production processes are documented without gaps and in addition repeatable standards should be integrated in the production.

Robots are increasingly being used in the production process for series production processes. However, there was a need in the area of intermediate and final cleaning. If these cleaning processes are not performed faultlessly and reproducibly, surface contamination on the instruments can result in quality deterioration during the further production. In other words, the instruments possibly show patchy surfaces after the final cleaning and/or in quality tests.

As almost every individual instrument is subjected to a critical quality inspection, spots occurred in the past after the cleaning

However, it was still completely unclear whether the cleaning was insufficient or not correct, whether the water quality was perfect or even the cause should be looked for in the raw material.

"Therefore we contacted the company Elma in Singen at the beginning of 2012", remembers Armin Maier, Marketing, Sales and Product Management Manager at Allgaier. "Ultrasonic cleaning is clearly technically and functionally superior to other methods for instruments with complex design". After analysis of the current situation, it was clear that two very different cleaning problems occurred in the production process. The patches were analysed and the tasks for system and process were formulated in a requirements specification. Accordingly, the instruments already had to be cleaned more and more intensively during the manufacturing process in intermediate cleaning steps. The following joining processes (for example welding) then result in repeatable and reproducible qualities. This process which can be validated was filed in the QM documentation after implementation. After completion, the instruments should also be finally cleaned without exception and ideally also protected against corrosion.

### Intermediate and final cleaning in two systems

The individual requirements were tested jointly with the specialists from Allgaier in the Elma laboratory. Numerous series of tests were performed and the cleaning results were assessed microscopically and using test liquids.

"After the production process had been reproduced on a laboratory scale, the results were assessed by us favourably. It was found that the intermediate and final cleaning should logically be performed in two completely separate systems. The intermediate cleaning is basically preliminary cleaning.

The intermediate cleaning has been optimised using suitable peripheral equipment (for example oil separator, filter technology) and the service life of the cleaners has been environmentally compatible and economically usefully extended.

In addition to the intensive fine cleaning, the final cleaning required an optimised rinsing process. The ultrasonic baths and the daisy-chained piped sinks clean complete product baskets free of patches and completely automatically (robot pass-through system). The instruments are then dried free of patches in the last sink. Corrosion protection was also required during this last production step (final cleaning before the packaging). "We certainly did not want any particles or chemical residues on the instruments for shipment", says Maier. "The users in the hospital or in the doctor's surgery should be able to channel the instruments directly into the circulation process, sterilise them and use them medically".

Therefore, the system obtained a sink for active passivation with citric acid in a further process step. The passivated metal surface is thus optimum bare metal and resistant to corrosion by oxygen. In the meantime, the system has been in use successfully for seven months.

The instruments shipped to more than 80 countries arrive in perfect condition and completely free of corrosion. Furthermore, the ultrasonic systems of the type X-tra Line are modularly designed. If the requirements at Allgaier change in the future or the material and production throughputs increase, they can be practically expanded easily and economically.

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