



WORLD OF MEDICAL DEVICE  
MANUFACTURING  
**PROCESS**  
QUALITY FACTORS

**PART**  
**2**

INSTRUMENT REPAIR EXPERT



BEYOND  
CLEAN



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Aesculap Technical Services

*Beyond Clean Instrument Repair Expert™*

## WORLD OF MEDICAL DEVICE MANUFACTURING PROCESS - PART 2 QUALITY FACTORS

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**Choice of Quality Materials:** To help ensure quality, the Original Equipment Manufacturer (OEM) selects the correct raw materials for the production of surgical instruments. While stainless steel may be used, materials such as medical grade aluminum, titanium, and a variety of peek or plastic-type products may also be found in the manufacturing process.

There is a lot of science and thoughtful engineering behind the use of certain types of materials, for the production of specific parts, which are used in the manufacturing of surgical instruments. Aluminum, for example, may often be used in the production of the handles. It may also reduce the overall weight of the instrument and the material itself is also known to be highly resistant to rust. The other materials have features and benefits that can help prolong the lives of surgical assets.

**Tight Tolerances:** For the right reasons, the OEM should hold itself to high standards and tight tolerances when it comes to manufacturing surgical instruments. Depending on the product and its intended use, those criteria might be measured in thousandths of an inch. The precision factor in the manufacturing of medical devices is very important. After all, the instruments are expected to not only last a long time in the case of reusable products but also to deliver consistent performance.

**Strict Inspection Criteria:** Finally, those materials and final products need to be put through a series of rigorous quality tests. The choice of the right materials and tight tolerances, make up only part of the overall manufacturing process. In the end, OEM needs to make sure that products are properly inspected and safe to use. That's where the quality control (QC) checks come into play. The QC department is responsible for doing the final inspection and help ensure that surgical instruments are meeting the highest quality standards before they can be released to the market.

Have more instrument repair questions? Contact Pawel at: [pawel.szczygiel@aesculapusa.com](mailto:pawel.szczygiel@aesculapusa.com)

*Beyond Clean Instrument Repair Expert™ Biography:*

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Pawel is a well-established Marketing Manager responsible for Aesculap Technical Services division in the U.S. With over 28 years of experience working in the medical field, Pawel has a wealth of knowledge in manufacturing and service of medical devices.

Pawel completed his 5-year apprenticeship program (in Poland and Germany) to become a Master-craftsman in manufacturing, engineering, and service of surgical instruments. He is highly motivated and goal driven individual who has in depth knowledge about medical products.

Pawel is an accomplished leader with team of experts whose goal is to provide excellent service to clinics and hospitals across the nation. His goal is to become a solution provider who understands the industry and cares about the patient's outcome. Pawel is innovative and highly skilled individual who focuses on quality and precision.

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