



# WORLD OF MEDICAL DEVICE MANUFACTURING PROCESS

## PART 1

### SURGICAL INSTRUMENT PRODUCTION

INSTRUMENT REPAIR EXPERT



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Pawel Szczygiel | Marketing Manager  
Aesculap Technical Services

*Beyond Clean Instrument Repair Expert™*

## WORLD OF MEDICAL DEVICE MANUFACTURING PROCESS - PART 1 SURGICAL INSTRUMENT PRODUCTION

*Pawel Szczygiel | Aesculap Technical Services*

**Research & Development:** The life of a surgical instrument begins with research and development. During this first stage of manufacturing, engineers work hard to produce the most innovative and groundbreaking ideas on products that will not only need to meet market demands but are also expected to set the highest standards for the medical device industry.

**Testing & Validations:** The manufacturing process doesn't just end with research and development, the next steps should involve prototypes, tests, and validations. The manufacturer strives to deliver instrumentation that will not only provide innovative technology, but most importantly is safe for the end user and the patient. That's the reason why this stage of the process is so vitally important.

**Quality & Regulatory Compliance:** We must not forget about the quality and regulatory departments who ensure compliance with regulations and best practice guidance in the verification and validation process. While regulatory affairs professionals can serve a critical function throughout a medical device's product lifecycle—leading premarket strategy, drafting regulatory submissions, and ensuring post-market compliance—quality control can be the final line in the medical device manufacturing process.

**Production:** Only after the pre-production quality systems and checks are completed, may the manufacturing process of medical devices and surgical instruments begin. It can take years for new products to be developed and released into the market. The Original Equipment Manufacturer (OEM) is often faced with strict FDA, ISO and many other compliance regulations that must be met before new products can be launched. This is to ensure that only safe-to-use products reach 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:*

**PAWEL SZCZYGIEL**

**MARKETING MANAGER  
TECHNICAL SERVICES**

**AESCULAP®**



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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