

# Medical Range

Global Leaders in Providing Implant Processing Systems to the Medical Industry



## Expertise

Optimal Technologies are known globally as a leading supplier of implant processing systems within the medical industry across a variety of applications including medical devices and orthopaedic implants etc. We provide systems to some of the world's best-known medical implant companies across the world.

Our highly knowledgeable and experienced team members provide our customers with the confidence that each system is built to our exacting standards.




**We pride ourselves on the level of expertise and experience of working in the medical implant industry, providing in-process cleaning, vital parts inspection assurance, all the way to final cleaning and passivation**



## Lean and Efficient

We have been very selective with our supply chain to make sure that our suppliers are local to our manufacturing facility, which means a reduction in their travel reduces our carbon footprint during the manufacture of our systems. We constantly review our processes to find other ways of reducing our carbon footprint.

**We're fully aware that space is often at a premium, so our systems have been specifically designed and optimised to provide the required throughput without sacrificing valuable manufacturing floor space through their compact footprint**



**Our implant processing system range provides full transparency with real-time performance monitoring & process validation towards smart manufacturing within FDA environments**

## **Trusted Partners**

With over 20 years' experience in providing implant processing systems to the medical industry, we pride ourselves in the relationships we build with our customers, providing a long-term partnership throughout the life of their equipment. We can provide expert knowledge on the best solution to suit the requirements of any size manufacturer regardless of the product requiring precision cleaning.

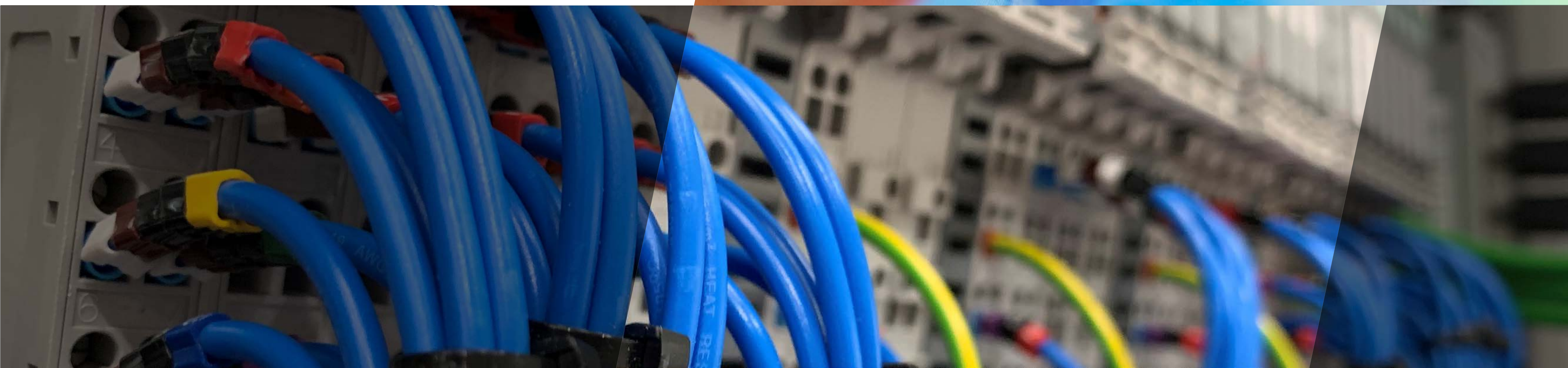


## Helpful and Flexible

Once we have installed a customer's system, we train their teams on production-ready elements such as; start-up, processing software, on-going and preventative maintenance.

Once complete, our sign-off process gives our customers the assurance that all their teams are fully trained and competent in operating the system.

Our software allows full recipe flexibility, allowing the customer to design a recipe in-line with their processes, offering multiple points of variability throughout each stage.





## Tailored Solution

The range of systems available means that our design team can tailor a solution in response to the URS provided by the customer, demonstrating compliance with mandatory functionality, industry and governing body guidelines (FDA, CFR, GAMP, GxP etc.) environmental, health, safety and sustainability requirements (EN ISO 13849-1:2015, EN60204-1:2015 etc.) and business requirements.

**Allows customers to choose from a number of configurations throughout the range, based on their capacity requirements**

## Requirement Compliance

Our systems exceed customers' specific requirements, whether they're operational, functional, process, technical or calibration.

- System and Product OEE
- Controlled and repeated cleaning process
- Control of global settings of mechanical agitation
- Comprehensive cleaning of implants to meet customers' visual inspection test methods
- Control of process variable settings e.g. time, temperature, ultrasonic power & conductivity
- Fixed position HMI (Human Machine Interface)
- Load/unload conveyor
- Automatically distinguishes alarm levels
- Optimal Technologies provides customers with all the necessary sign-off procedures and paperwork including FRS, FDS, HDS, SDS and FAT



## Powerful Cleaning

Every system in the range is fitted with adjustable ultrasonic power frequencies depending on the application, gently scrubbing the surface with millions of microscopic cleaning implosions.

# In Process Cleaning (IPC)

Our IPC systems have been designed to clean medical implants between production processes. The innovative design and the processing delivered is comprehensive. The compact construction of the system means that it can be positioned in small production areas, enabling it to be installed in manufacturing cells where previously, a centralised cleaning facility would have been used, enabling improving quality and efficiency.

## Features of the IPC include:

- Unloading conveyor
- Colour touch screen monitor HMI (Human Machine Interface)
- On-board DI water purification as standard.
- Automatic process transfer technology using vertical oscillation during cleaning and rinsing
- Slow lift-out on final DI rinse
- IR drying and air knife
- User safety is paramount, with safety interlocks and password protection
- Air extraction and Class 100 HEPA filtration as standard
- Overall Equipment Effectiveness (OEE) is maintained via remote access to ensure productivity remains high
- Can be designed to UL standards



# Final Clean and Passivation (FCP)

Our FCP units provide real-time and historical trending of process parameters, combined with data logging to capture key metrics to ensure a smooth audit process via accurate traceability through barcode or RFID technologies.



## Features of the FCP include:

- Optional software connection to up-stream internal systems
- Real-time data retrieval for smart manufacturing and data analytics which complies with 21 CFR Part 11 standards
- All pipework and fabricated parts have the highest grade 316L stainless steel
- Seamless tri-clover fittings, ensuring cleanliness is maintained throughout the system
- Digital HMI for recipe design and performance monitoring
- Remote camera accessible from the users' phone or laptop enabling process monitoring including filtration, temperature and process times etc
- Can be designed to UL standards

# Fluorescent Penetrant Inspection (FPI)

Correct preparation is vital towards the quality of the finished part before penetrant inspection; therefore, our cleaning and monitoring processes allow parts to be processed to the highest standard to remove unwanted reworking, over processing and scrap rates commonly seen at this stage. The fluorescent penetrant is then applied to the surface of the implant and allowed time to penetrate flaws or defects in the material, followed by a 'dust storm' developer process identifying the smallest of imperfections.

Our robust variable ultrasonics ensures that the penetrant is removed only from the surface of the material and not from inside any identified flaw.

## Features of the FPI include:

- Baskets are monitored throughout each stage of the process using either a barcode system or RFID tagging
- Programmable dwell time
- Batch reporting for real-time process reporting
- On-board monitoring system in-process reporting capability
- Tri-clover stainless steel pipework and fittings as standard
- Optional Teflon<sup>®</sup> coated tanks with environmental monitoring
- Can be designed to UL standards



# Final Clean Systems (FCS)

Using a basket in-line conveyor, loading stations will be fitted with proximity sensors for increased user safety and outlet conveyor tunnels are fitted with a cooling, touch button interlocked mechanism for safe handling.

With high capacity sump tank for chemical and rinsing, acid density and filtration flow rates are captured to combine accurate, data acquisition and accurate system monitoring.



## To enhance traceability, the FCS has:

- Barcode scanning, so batch numbers are captured
- RFID technology for traceability and full alarm monitoring,
- Optional camera capture via smartphone, laptop or tablet.
- For ease of maintenance, all pumps and filter housings are fitted with isolation valves for increased overall equipment effectiveness (OEE)
- Can be designed to UL standards



**MADE IN  
BRITAIN**

Compliance | Validation | Quality

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