

SUCCESS STORY 82

SILICONE BREAST IMPLANTS



Q

How was a multiphase oven used in the manufacture of sterile breast implants surveyed?

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Situation and background

In the production of silicone breast implants, different products are required to be taken through very accurately controlled, lengthy heating cycles. This gives the implants their required physical characteristics while maintaining their sterility. To meet current medical validation protocols, such processes need to be accurately surveyed at 16 measurement points. Maintaining process sterility was a requirement for any measurement solution.

The winning solution

- Dual Datapaq® MultiPaq21 logger was used to provide 16 accurate type T measurement channels, which is a requirement for medical applications.
- Logger correction factors were applied to ensure optimal system measurement accuracy.
- A special barrier design, based on TB5817, was used to hold two loggers and provide protection for the duration of the process.
- The barrier's sealed faceplate and IP67 thermocouple fittings prevented outgassing issues in the inert process.

Savings made

- This cost effective, in-house validation solution enabled the end-user to guarantee product cure quality and eliminate risks to patient health.
- Significantly reduced product reject costs resulted from process optimization.
- Regular process validation has minimized the risk of future litigation risks.

KEY FACTS

Customer's End Product
Silicone breast implants

Max Temperature Reached
Phased heating up to
180°C/356°F

Duration of Process
Up to 6.5 hours

PRODUCT AND BENEFITS



MultiPaq21 DP2182
TB5823 thermal barrier
Food core probes
Oven Insight™ software

- Single system providing 16 measurement channels
- Thermal protection of logger guaranteed over entire 6.5 hour process
- Oven Insight Software allows application of logger correction factors to guarantee optimal measurement accuracy