



## **White Paper for Medical Bag sealers – OK International Corp.**

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### **Selecting and Applying the Right Bag Sealer Technology**

Bag Sealing equipment plays a vital role in today's manufacturing. Applying effective heat seals to the package of terminally sterilized medical devices, is arguably the most critical step to ensure the aseptic presentation of a product when it comes into contact with an end user or patient. No matter how robust the sterilization and disinfection process, if the packaging and seal closures of a medical pouch are compromised, there is significant risk of product contamination during shipping and storage that could pose serious danger to the end user.

This white paper reviews the relevant regulatory standard for medical heat sealing and discusses some of the important considerations that should go into implementing an effective validation process. After covering some of the design characteristics that ought to be prioritized when considering the abovementioned process variables, it continues to make the case that process validation for medical heat sealing needs to include a broader range of parameters – including seal-area wrinkles, band breaks, and label applications – beyond the traditional parameters, temperature, dwell time and sealing pressure.

### **Today's Technologies**

OK International's line of medical pouch/bag sealers assures consistent and reliable heat sealing of medical pouches. All of OKI's medical sealers are validatable and feature process control for all machine functions; including dwell time, temperature, pressure on seal wheels, and pressure



on seal bars, band breakage and quality of seal. All machines have calibratable instruments and also feature PLC based data collection and system control. In compliance with the new **UDI/GS1** mandate for medical devices, our new designed Medical Sealers, which features comprehensive controls and diagnostics to satisfy stringent **FDA** standards, is capable to meet these demands.

## Validating Medical Heat Sealers

Validating the heat sealing process is thus critical both to comply with regulatory oversight and to be confident in the overall quality of the final product. But what is the clear definition of validation? It is basically all components of the sealing process that influence package integrity and must be monitored, measured and controlled. Also the equipment must perform the heat sealing function in a repeatable, invariable manner so the final product quality is consistent with predetermined standards.



The three critical variables for medical heat sealing validation (ISO 11607-2) have been dwell time, pressure and temperature. An effective tool to meet this component of the standard is programmable logic controller (PLC), which can execute the alarms, have the machine stop and display immediate machine status. A PLC can also perform data logging that time stamps alarm history, which is benefit from a validation point of view. Additionally, the standard indicates that critical process instruments and sensors must be calibrated.

Given the demands of the validation process, there are some important design features that are optimal for validation that should be considered when specifying a piece of heat sealing equipment.

For example, for measuring temperature, a heat sealer that monitors all heating bars individually, rather than just one, affords enhanced process controls.

Pressure reading, in the case of a continuous band sealer, are more accurate if pressure is delivered through air solenoids which can be calibrated and pneumatically controlled to provide consistent sealing pressure.

Dwell times, reflected in speed measurements, should be measured and monitored with a PLC to offer a digital speed read out allowing real time speed monitoring.

While crucial for an effective seal necessary to ensure sterility, it is possible to thoroughly validate a packaging process for these three parameters and still produce faulty seals that could ultimately imperil the safety of patients. There are other areas where process control could fail and threaten package integrity.



Wrinkles can occur throughout the seal even if temperature, pressure and dwell time are all operating within accepted parameters. An effective validation tool for wrinkle detection, is the wrinkle detector. This feature can sense a wrinkled seal, trigger an alarm and will have the machine go in reverse. If specified, an alarm can prompt a bag direction reversal and reject a bag back to the operator and then reverse back to

normal operating directions, once the defective bag has cleared the machine.

Furthermore, the band integrity is a critical factor not captured through traditional validation procedures. A band could break, but pouches could have been processed through the sealer before the thermocouple has had time to acknowledge the temperature change. A continuous band sealer must monitor band integrity and be integrated into the PLC system, to display current status, trigger alarms and stops when a band breaks or is missing.

### **Band sealers The Classic Solution**

Band sealers are still the state-of-the-art solution for numerous sealing applications.

They feature continuous motion and a relatively high degree of automation. Typical band sealers run up to about 65 feet per minute.

By contrast, one high-capacity band-based Supersealer model from OK International, (OKI) uses four heaters and other design innovations to allow speeds as high as 100 feet per minute.



Of all available technologies, band sealers can handle the widest variety of bag materials, from paper, poly, and foil to Tyvek®. They're the recommended sealing solution for Tyvek® pouches and Tyvek®/Mylar® pouches. Because of the hills and valleys in Tyvek®, the physical contact the band provides is essential. The bands hold the film, so heat can't cause wrinkling or shrinkage during the sealing process.

This provides specific advantages for the medical industry, which requires 100% perfect seal with no wrinkles. All these challenges can be met by OKI's Supersealer MBS.

By contrast, OKI medical sealers feature efficient, compact, mobile profiles. With features such as stainless steel construction, motorized height adjustment, external ports for calibration and lift hoods, they're specifically designed to make access effortless and maintenance easy. (as well as infrequent)

The Supersealer MBS is designed specifically for medical device manufacturing. It offers a superior controls package, featuring with touch screen monitoring of all variables, easy calibration, and touch screen setting changes, as well as an optional data acquisition package for recording of pouches being sealed. Finally, OKI pioneered an innovation that is now an industry standard: automatic reverse if parameters depart from settings. The Supersealer Medical Sealers never allow a pouch to be sealed outside its parameters.

### **Hot air sealers an alternative format**

Hot Air Sealing is another platform OKI has for their medical sealer. The Supersealer MS has all the features and benefits as the Supersealer MBS.

The hot air medical sealer is ideal for medical companies who seal, poly to poly, paper or foil pouches.

The sealer has four heating capsules. A high velocity fan pulls ambient air in which is fed into the manifold and passed over the cartridge heater and brought up to heat that is set. This air blows onto the film, passing it in front of the heating capsules. The pouch/bag then passes between to seal wheels to complete the seal process. There are no bands to change or gap to keep; it is an alternative solution to medical pouch/bag sealing.

### **About the OK International Group**

From its start in 1982, the OKI Group has grown into a leading global manufacturer of integrated packaging automation systems.

The OKI Sealer Division specializes in continuous heat sealing platforms. With its plants in the U.S. and Europe, they manufacture the world's most advanced hot air sealers, band sealers and integrated conveyors. Today, thousands of OKI's innovative products provide successful sealing for a wide range of demanding "end-of-line" bag and pouch applications around the world.

### **About the Author**

With more than 30 years of experience in applying hot air and band sealer technology, Ann Marie Kellett is the Product Manager for the Sealer Division at OKI.

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