Heat Sealers: Be Consistent to Minimize Risk

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How to keep a close watch on your sealing parameters and conditions.

When it comes to heat sealing, process consistency is the medical device manufacturer's friend. Any deviation from validated sealing temperatures, dwell times, pressures, and even positioning and feeding could spell trouble.

Operator training and control are essential to maintaining such consistency. But when juggling different packages and products, as is common in low-volume medical device packaging runs, following established parameters after change over can be tricky.

Heat sealing technology suppliers are offering some assistance. "The current focus for most MDMs is reducing or eliminating risks in their process," says Lynne Barton, senior account executive for CeraTek, a SencorpWhite brand (www.sencorpwhite.com). "While a small percentage of companies need to address unusual deficiencies in their SOP, most MDMs have very similar issues that can be resolved with readily available, standard auxiliary equipment."

As an example, Barton explains that SencorpWhite has provided sealers with internal pouch material sensors to ensure that the correct set of parameters is running for a particular pouch material. "If the set of parameters currently loaded on the sealer is for a Tyvek/poly pouch, for example, and the operator puts a foil pouch into the seal area, the sealer will alert the operator that there is a pouch material mismatch and prevent the sealer from cycling. Alerts can be programmed to be self-resetting. In this case, alerts will reset themselves by simply removing the incorrect pouch from the sealer. Alternatively, the alerts can be programmed to escalate to a full alarm condition requiring a keyed reset immediately upon seeing a mismatch or after a timer has elapsed.

Since these mismatches do not affect the hermetic seal on the pouch, Sencorp-White provides flexibility to the MDM to handle preseal mismatch alarm conditions to their preference."

OK International's (OKI; www.OKSealer.com) newest model of the Supersealer MBS Medical Band Sealer features a color touch screen display showing the set points and real-time parameters at all times, explains Ann Marie Kellett, OKI's vice president. "If a parameter is outside the set range, the machine will run in reverse until this is resolved. The display shows the temperatures, speed, and air pressures, and a pop-up alarm banner provides accurate and immediate information, eliminating the requirement to search for errors," she explains.

The system allows MDMs “to write an uncomplicated protocol for straight forward and easy validation,” Kellett adds. “External ports allow instruments to be plugged in for the calibration of the machine, even when the machine is running. This also enables the customer to do easy, random checks.”

Proper packaging material positioning can also be encouraged with machinery. “Ensuring that the pouch is properly aligned so the seal does not run off the top of the pouch is easily achieved using two or three internal sensors,” Barton explains. “The sensor locations can be adjusted to handle multiple seal positions for various pouches. The sealer is programmed to prevent a cycle from starting unless the pouch is properly positioned in the seal area and the pouch sensors are met. Instantaneous live feedback with visual indicators on the HMI enable the operator to see when the pouch is in the correct seal position so the cycle can be started.”

Image of the Supersealer MBS courtesy OK International

The Supersealer MBS features a wrinkle detection system that prevents bags or pouches to be sealed if there is a wrinkle in the bag or product in the seal area, Kellett explains. “In such conditions an alarm will activate and the bag will be reversed out of the machine,” she says.

KOCH Packaging Systems Inc. believes modular machine design can help end-users achieve flexibility for changeover along with process control. “With the growing interest and need for a machine that can handle a variety of package types and designs, the design group at KOCH has come up with a veritable ‘menu card’ of available optional stations to provide various combinations of automation,” says Mark Mosher, president, U.S. operations, KOCH Packaging Systems. “This flexibility makes it possible to tailor the machine operation to the exact needs of our clients and assist them in fulfilling their individual requirements.”

KOCH’s latest offering includes a combination of operations that can be integrated to its standard KDT sealing machine, a four-station rotary sealing system that can also be configured for forming blisters from precut sheets of formable film. “The sealing station is configured in such a way to make the tooling inexpensive and easy to change for high flexibility of multiple SKUs,” says Mosher. “This combination makes the KDT ideal for developing new package samples for market studies and can also provide for medium-volume production of medical devices, healthcare products, cosmetics, and consumer products. For the medical and pharmaceutical markets, full validation documentation and testing are available for the system.”

Automatic blister placement from a magazine allows for the operators to be more efficient and accurate when placing the products into the blisters, and insert placement from a magazine enables automatic placement of an information insert for a package with a film or paper lid material, Mosher explains.

Mosher adds that to place a flexible lid material on a blister, the KDT sealing systems can employ a station to automate the process. The system will unwind the lid material from rollstock, cutting it to length with either a straight cut or rounded corner bone punch, and then transfer the lid material over to the filled

blister on the sealing tool. “This system can be used with Tyvek, paper, foil laminates, film laminates, or any other heat sealable material in roll form,” he explains.

Labeling can present challenges, too, and they could escalate as more and more MDMs find themselves adding Unique Device Identifcation. “MDMs with labels affixed to their pouches sometimes have issues with mislabeling or incorrect placement of labels,” says Barton. “Bar code scanners and/or imaging scanners can verify label accuracy and location on a particular pouch. If the incorrect label is applied to the pouch, the sealer will alert the operator that there is a bar code/label mismatch. If the label is not in the correct area of the pouch, the sealer will alert the operator that the label is missing. Likewise, these alerts can be programmed to the MDMs preference.”

The unwind system of KOCH’s KDT machine can be fitted with various types of inline printers to apply variable text, date/lot codes, and even full web printing, Mosher adds. “Vision inspection systems can also be installed for verification of printed information, confirmation of material preprinted codes, or tracking lot information to provide unique databases for traceability purposes,” he says. “For preprinted materials, the machine will automatically detect the eye spot and cut the material accordingly to provide the registered printed lid on each blister.”

Barton shares that SencorpWhite is working on the next generation of risk mitigation. “SencorpWhite is currently in the R&D phase for a fully automated pouch sealing and inspection system. While SencorpWhite is designing the basic system to be able to handle 90% of the MDM industry’s pouches and mitigate most standard SOP risks without any customization, the system will also be flexible enough to be tailored to address specific SOP flaws if required,” she says.