

Port Sealing: An Effective Heat Sealing Solution

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Heat sealing is the process of sealing one thermoplastic to another similar thermoplastic using heat and pressure. The direct contact method of heat sealing utilizes a constantly heated die or sealing bar to apply heat to a specific contact area or path to seal or weld the thermoplastics together. Heat sealing is used for many applications, including heat seal connectors, thermally activated adhesives and film or foil sealing.

Common applications for the heat sealing process

Heat seal connectors are used to join LCD displays to PCBs in many consumer electronics, as well as in medical and telecommunication devices. Heat sealing of products with thermal adhesives is used to hold clear display screens onto consumer electronic products and for other sealed thermoplastic assemblies or devices where heat staking or ultrasonic welding is not an option due to part design requirements or other assembly considerations. Heat sealing also is used in the manufacturing of blood test film and filter media for the

blood, virus and many other test strip devices used in the medical field today. Laminate foils and films often are heat sealed over the top of thermoplastic medical trays, Microtiter (microwell) plates, bottles and containers to seal and/or prevent contamination for medical test devices, sample collection trays and containers used for food products.

A growing market for heat sealing applications over the last decade is in the manufacture of medical and fluid bags used in the medical, bioengineering and food industries. Fluid bags are made out of a multitude of varying materials such as foils, filter media, thermoplastics and laminates. Material selection for the bags is based upon their intended application or compliancy requirements (see sidebar on page 38).

Medical bags are used in an array of applications, from the dispensing of medicine to the collection or transfer of blood or other biological media. The usage of these fluidic bags and the flexibility they have provided has been expanding into the consumer products and food industries over the last decade.

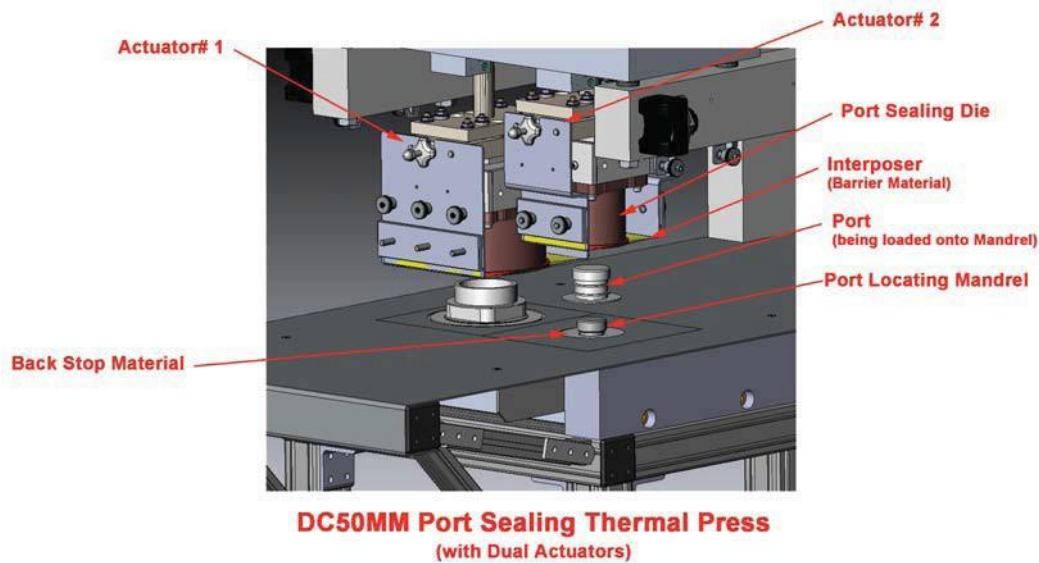
The market expands into medical and fluid bags

The growth of the converting and laminating equipment technologies and processes have created many exciting new opportunities for the production of new films and laminates used to make medical and fluid bags. The laminated films and bag materials specifically are engineered to have very colorful print options and artwork on the outside layer, while having food or medical compliancy properties for the internal material and structure of the bag. This provides manufacturers and food producers with new delivery and marketing opportunities for their food and liquid products.

one feature these fluid bags have in common is the need to have ports for getting fluids in and/or out of the bags. Ports, tubes or fittings are installed and heat sealed or welded into the bags. The ports, tubes and/or fittings for these bags most often are attached with the heat sealing and RF welding tech-



Fluid bags use ports, tubes and fittings to get fluids in and out of bags. These most often are attached using heat sealing and RF welding.



nologies, but impulse and ultrasonic welding also are commonly used. The heat sealed ports must have a hermetic seal.

Elastic ports and fittings that are sealed onto the media bags also often are called port plates, port discs, end dispensing fitments or boat fitments. These various ports and fitments are manufactured by injection mold companies worldwide and are readily available in standard shapes, styles and sizes. Flanged port plates with barbed port for tube installation are available from $\frac{3}{16}$ " to 1". Dual barbed ports also are available for applications that require tubes inside and outside of the bag. Ports with screw cap and other dispensing configurations are available.

Boat fitments or end dispensing fitments are wedge-like pieces that are sealed into an open end of a bag. Boat fitments usually have multiple ports for multiple tubes or connectors. Custom port configurations and/or custom boat fitments can be manufactured by an injection molder to meet any specific engineering or manufacturing requirement.

How does the heat sealing process work?

The heat sealing process for ports requires a heat seal die or blade designed to work with the specific port or fitment. The port usually is located over a mandrel or fixture during the heat sealing process. Heat sealing usually is performed with the bag or film material over the port while it is on the

Standards Compliance

FDA and USDA compliancy are two of the most common level of compliancy requirements for bag manufacturing. This compliancy is for food industries, as well as the generic collection of liquids, as set forth by the FDA guidelines. The Food and Drug Administration (FDA) is the regulatory agency of the United States government that is responsible for determining how materials may be used in contact with food products. The United States Department of Agriculture (USDA) regulates manufacturing, packaging and handling practices in the agricultural food industry. The most common plastics utilized in the manufacture of the Ports and Bags used for this level of compliancy are:

- LDPE (Low Density Polyethylene)
- HDPE (High Density Polyethylene)
- PVDF (Polyvinylidene fluoride) or Kynar®

- PC (Polycarbonate-FDA grade)
- Nylon 6 (Polycaprolactam, Polyamide 6)
- Nylon 6/6 (Polyamide 6/6)
- PPO (polyphenylene oxide – styrene) or Noryl®
- PET-P (Polyethylene terephthalate – polyester)
- PTFE (Polytetrafluoroethylene -FDA grade) or Fluorosint®
- PBT (Polybutylene Terephthalate) or Hydex®

USP Class VI is the highest standard level of compliancy for the manufacturing of medical bags, as set forth by United States Pharmacopeia (USP) guidelines and requires the most extensive testing for conformity of materials. Some of the most common materials utilized in the manufacture of the ports and bags for this level of compliancy are

- PVDF (polyvinylidene fluoride) or Kynar®
- PC (polycarbonate-FDA grade)

mandrel or fixture. There also usually is a layer of interposer material to prevent sticking between the heat seal die and the film material during the heat sealing process.

Some port heat sealing applications require an engineered material to be underneath the port to act as a back stop or heat sink for the heat sealing process. The back stop material can be a compliant- and/or a silicone-based material. This will allow the thermal conductivity of the die to pass the heat through the film or bag material and through the flange of the port, while squeezing the parts together to achieve a hermetic heat seal. Material selection for the back stop must be selected based upon heat seal testing of the bag and port materials selected.

The ports and fitments are installed either on an open or closed bag. The tooling and heat seal process for an open bag or single-layer film is the most simple when compared to other applications. The tooling can be an open or flat format with just a part location feature. Closed bags are more complicated and require some sort of knee or mandrel that allows the bag to be placed over it to locate the entire bag relative to the port location to be heat sealed.

End dispensing or boat fitments require heat sealing into the end of a closed bag requiring multiple mechanisms and heat seal dies. The heat seal tooling for the end dispensing or boat fitments usually requires heat sealing completely around the fitment or around the open end of the bag from both sides

during a single cycle. Sometimes, this heat seal is performed while sealing the entire perimeter of the bag itself.

Since many of the bag applications are for storing medical fluids or dispensing medicine, a higher level of assembly equipment and validation of the heat seal processes are required. When a higher level of accuracy is required, then the heat seal equipment must have an appropriate level of validation and control features. Heat sealing systems with linear or servo actuators integrated into the machine along with process control alarms have the highest ratings for accuracy and repeatability.

For higher production volumes the heat sealing equipment and converting equipment can be combined together into a custom automation system. These systems are the most complex, as they will require a matrix of parts and assembly combinations. These automation systems will produce the greatest array of parts with a minimum amount of operator interaction. This will help medical bag manufacturers to meet the higher levels of certification and compliance, while reducing and/or eliminate failures due to operator error. •

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