Hot-melt adhesives for medical packaging

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ABSTRACT: Medical packaging, or packaging for disposable or implantable medical devices, has essentially three components: the blister or bottom web, the lid or top web, and the adhesive that holds the package together. The top and bottom webs must be barriers to bacteria, dirt, and moisture, and all three components must function together to deliver the device to the final customer in a "clean" and undamaged condition.

The blister and lid are often chosen first using a variety of parameters including puncture resistance, appearance, cost, printability, and equipment constraints. The adhesive, usually chosen last, must be strong enough to hold the package together, must be resistant to stress and penetration, and must facilitate easy opening. Additionally, when the package is opened, the adhesive must leave clear evidence that the package integrity was not compromised during sterilization, shipment, or storage. It must be able to accommodate, and sometimes compensate for, the limitations of the other two components.

Hot-melt adhesives can be formulated to meet the demands of this type of packaging, in part due to the nature of the ingredients now available, with careful formulation and processing.

KEYWORDS: Adhesives, aseptic packages, blister packs, bonding strength, hot melts, medical surgical supplies, peel strength, specifications.

Hot-melt adhesives are used in many areas of industry including box closure, labeling, packaging, assembly, and construction. This paper specifically focuses on the use of hot-melt adhesives in the packaging of medical devices. These adhesives are usually provided in the form of heat seal, adhesive-coated nonwoven polyethylene (e.g., Tyvek®, paper, film, or foil). Medical packaging, or packaging of implantable or disposable medical devices, consumes a relatively small portion of the total market for hot-melt adhesives, but the technical requirements are very demanding because an adhesive failure can endanger human health or life. Additionally, customers in the health care industry require ease of use, predictable performance, and ever lower cost.

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Medical packaging

Packaging needs

Companies that package medical devices have unique requirements including a reliable sterile barrier, tamper evidence, ease of processing, consistent quality, timely delivery, reasonable cost, and responsive technical support. Most of these needs, with the exception of the sterile barrier and tamper evidence requirements, are similar to those of other customers. The following package component breakdown describes the role of hot-melt adhesives in this market niche.

Package construction

Packaging for disposable or implantable medical devices is made up of three components: the blister or bottom web, the lidding or top web, and the adhesive that holds the package together. There are many combinations of top and bottom web materials; the adhesive is discussed later in the paper.

Bottom web. The blister or bottom web is usually made of rigid or

flexible plastic or paper. It may be as little as 0.0254 mm or as much as 0.75–1.25 mm thick, depending on the product being packaged. A brief overview of some materials used for the bottom web or blister is shown in **Table I.**

Lidding. Options for the lidding, or top web, are nearly as numerous as those for the bottom web, with some of the same qualities and limitations. The possibilities include various grades of nonwoven polyethylene (such as Tyvek), many grades and types of paper, and some films. Some of their advantages and disadvantages are listed in **Table II.**

I. Blister or bottom web materials

Material	*Advantages*	*Disadvantages*
Flexible films: polyethylene films, PVDC/EVA films, coextruded films	Available with a wide variety of properties, low in cost	Less content protection and less distinct package formation
Rigid films: polyvinyl chloride, PETG, polystyrene & high-impact PS, SAN, acrylics, polycarbonate, rigid polypropylene	Good package protection, high-quality image, well defined thermoforming	Usually higher in cost, not as good for bulk or random packaging
Papers: Poly-coated paper, sterilizable kraft paper	Low cost	Cannot be thermoformed

Packaging choices

In developing the package for a medical device, the manufacturer often chooses the top and bottom webs first based on product protection, puncture resistance, cost, clarity, equipment constraints, and availability *(1)*. The manufacturer then tests a variety of coated top webs, searching for adhesive properties that fit the package requirements. This process may dictate that the adhesive's performance is based on the limitations of the preselected top and bottom webs. These limitations include sensitivity to heat, limited puncture or tear resistance, and process and equipment constraints.

Hot-melt adhesives

The remainder of this paper describes the advantages of hot-melt adhesives in relation to the seven customer requirements listed below. The adhesive must:

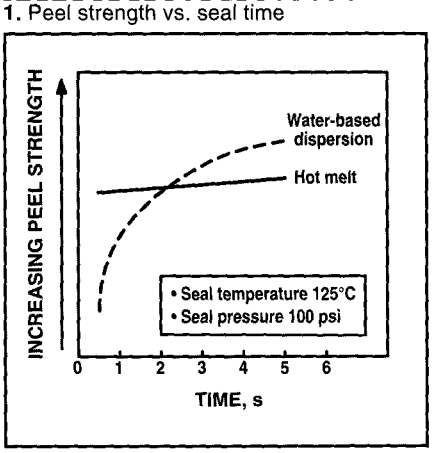
- Form a void-free seal as a bacterial barrier
- Leave a uniform adhesive transfer when opened for evidence of seal integrity
- Give a peelable bond with controlled strength
- Provide a broad sealing range for ease of use
- Retain the lid's porosity under 200 Gurley seconds
- Be nontoxic, meeting U.S. pharmacopoeia (USP) requirements
- Provide extended shelf life after ethylene oxide (EtO), radiation, or autoclave sterilization.

Discrete adhesive placement

One advantage of hot-melt adhesives for medical packaging is that they can be applied in discrete dots, lines, or patterns. The use of the dot pattern may at first seem to pose a problem in providing a void-free seal as a bacterial barrier. However, in actual use, the dots in the heat-sealed area flow together to form the necessary continuous barrier. A significant advantage of a dot pattern is that the porosity and flexibility of the coated material are retained as the dots cover only about 30–50% of the total surface.

Applying adhesive in patterns can also fill special user needs. A medical device manufacturer may require that the lidding be free of adhesive where it would normally be in contact with the device. This would require lidding with adhesive coating in the seal area and no coating in the device contact area.

1. Peel strength vs. seal time



Formulating options

The hot-melt adhesives used in medical packaging are similar in composition to those used in other applications. The major components in an adhesive formula include polymers, waxes, resins, antioxidants, pigments, and inert fillers.

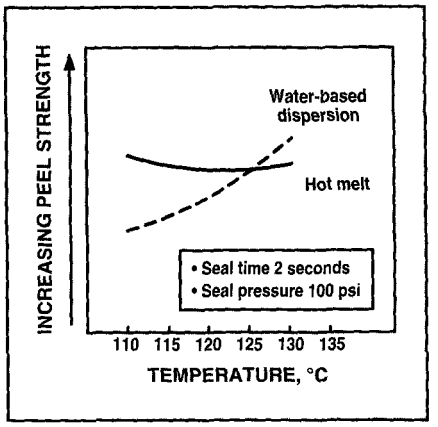
This paper focuses on the first three components, which make up the majority of the adhesive (usually 80–95% by weight). These components also have the greatest effect on the performance of the final product.

Base polymers for hot-melt adhesives include acrylics, ethylene vinyl acetates (EVAs), polyesters, polyethylenes, polystyrenes, and block co-

II. Lid or top web materials

Material	*Advantages*	*Disadvantages*
Synthetic nonwoven: Tyvek®	Proven bacterial barrier, puncture-resistant high-quality image	High cost
Peelable papers: latex-reinforced, nonreinforced, poly-coated	Low cost, less heat sensitivity, good printability	Less puncture- and tear-resistant, does not have bacterial barrier history of Tyvek
Various films: polyester, high-density PE, polypropylene, coextruded films	Low cost an transparency	No porosity for EtO or autoclave sterilization

2. Peel strength vs. seal temperature



polymers *(2)*. Microcrystalline waxes, polyethylene waxes, and petroleum waxes can be used with these base polymers. A few of the available resins are polyterpene resins, based on forest products; hydrocarbon resins, based on petroleum products; and liminene resins, based on citrus products.

These resins and waxes are available in a wide range of melting points. They can be blended in various combinations and percentages to yield a variety of properties and fill specific customer requirements *(3)*. This range of options allows an adhesive formulator to design an adhesive that bonds to specific plastics under special processing conditions. Hot-melt adhesives can also be formulated to give a specific peel strength with less regard for sealing time, temperature, or pressure. However, this is a disadvantage if packagers try to achieve a wide range of peel strengths by changing their sealing conditions.

Users generally need carefully controlled peel strengths under a broad range of sealing conditions. **Figures 1 and 2** show peel strengths for typical hot-melt and water-based dispersion adhesives. Changes in peel strength relative to changes in sealing temperature and time are shown. As the sealing time or temperature is increased, the peel strength for water-based dispersion adhesives rises rapidly. Under the same sealing conditions, the hot-melt adhesive's peel strength remains relatively constant. This is very desirable, allowing a manufacturer to produce consistent packages under a wide range of sealing conditions.

Special needs for paper lidding

One example of demanding requirements for an adhesive is in peelable papers for medical lidding. The adhesive must be strong enough to hold the package together during sterilization and transportation. It must not, however, be so strong as to tear the paper lid when the package is opened. Tears are unacceptable because the package may be opened in an operating room or similar sterile environment, and loose paper fibers from the nonsterile exterior of the lid could cause patient infection. The need for a strong adhesive used on a relatively weak paper was filled by a formulation that was adhesively strong but cohesively weak. These characteristics gave the adhesive a strong bond to the paper lidding and to the plastic film of 0.35–0.45 kN/m for durability during sterilization and transportation. When the package was opened, the adhesive failed cohesively with a force of 0.13 kN/m, leaving the paper undamaged. The adhesive residue left on the package flange is clear evidence of package integrity and content sterility.

Adhesives for joining rough surfaces

Hot-melt adhesives can also be applied in higher coating weights than are practical for water- or solvent-based adhesives. Coating weights can range from 5 g/m^2 to 50 g/m^2. A higher coating weight can facilitate medical device packagers' use of this product. A thicker layer of adhesive between the flange of the tray and the lid, for example, can act as a filler to compensate for irregularities in the lidding material, the bottom web, or the tooling used to form the seal. High coating weights can impart an additional advantage of absorbing shocks and vibrations when the package is shipped under severe conditions.

Biological compatibility

Another advantage of hot-melt adhesives is related to the materials used in their formulation. Most of these materials are chemically inert, especially with regard to biocompatibility. Most hot-melt adhesives do not react in biological systems and thus can pass USP Class VI requirements for implantation of plastics. This testing includes acute systemic toxicity, intracutaneous tox-

icity, and implantation tests. Biocompatability adds a degree of safety for the packager who may be concerned with the adhesive coating coming in contact with a device that is to be surgically implanted.

Thermal stability

A final benefit of hot-melt adhesives is their thermal stability. For most coating equipment, these adhesives must be formulated to withstand processing temperatures of 163°C for up to 72 hours. The term Q_{10} is an acceleration factor that is used to estimate the effects of elevated temperature exposure. If a Q_{10} of 1.8 is used in a standard accelerated aging formula, the projected life at ambient conditions (25°C) is 30.8 years *(4)*. The accelerated aging formula is:

$$S = (T_t \times Q_{10}^{t/10}) + T \qquad (1)$$

where

S = estimated shelf life, years

T_t = time exposed to elevated temperature, years

Q_{10} = acceleration factor

t = exposure temperature, °C

T = actual (chronological) age, years.

This level of thermal stability shows that most hot-melt adhesives are unaffected by normal ethylene oxide, radiation, or autoclave sterilization conditions and can be used confidently where packagers need extended shelf life.

Processing limitations

Hot-melt adhesives for medical packaging have some limitations. The range of polymer molecular weight that can be used is restricted by the equipment used to coat the materials. On most equipment, the adhesive viscosity at 165°C must be less than 100,000 cp. This limits the adhesive's performance at elevated temperatures, and packagers are always seeking adhesives with higher peel strength and/or higher temperature resistance. One practical constraint is that hot-melt adhesives are not always the least expensive alternative. However, they can be used competitively because of their inherent processing economy. Hot-melt adhesives are 100% solids, so they do not require drying or curing. They need only be melted, applied to the lidding material, and cooled. As a result, the equipment used for coating hot-melt adhesives can be relatively simple and inexpensive. A hot-melt adhesive applier can coat materials from 25 mm to 1.5 m wide; a simple hot-melt coater can be made for US$ 50,000 or less.

Summary and conclusions

Medical packaging is a very demanding market for any adhesive-coated material supplier. The variety of top and bottom web combinations used and the specific demands of the medical device packagers make it difficult to satisfy all of the performance and appearance requirements.

Hot-melt adhesives provide significant advantages due to several qualities:

- A wide range of ingredients available for formulation
- The ability to be applied in high coating weights and in dots, lines, or patterns
- The inert nature of the ingredients and thus the adhesives
- The formulated stability of the adhesives.

Hot-melt adhesives are uniquely suited to fill many needs of medical device manufacturers and, when carefully formulated or modified, are able to satisfy all their requirements. Materials coated with hot-melt adhesives are currently used in packaging devices ranging from catheters and shave preparation kits to hip joint replacements and pacemakers. Additionally, new materials, including polymers, waxes, and resins, are continually being developed and will be useful in formulating adhesives for the future needs of medical packaging.

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