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COVER STORY

Achieving Efficacy and Sterility in Flexible Packaging

Whether the priority lies in the sterilization method or the barrier level, packaging requirements can be easily met with a wide variety of material options.

Karen Berger and Dhuanne Dodrill


Photo by RONI RAMOS

PACKAGING PLAYS AN IMPORTANT ROLE in many industries, but few applications are as demanding as those found in the medical device and diagnostic industry. Packaging for medical devices may lack the glamour and glitz of that for consumer goods; however, nowhere else is package integrity as important. The job of the package is to maintain the sterility of the product through its intended shelf life, as well as ensure its efficacy at the time of use. The impressive range of flexible packaging materials available today helps to achieve these goals. This article will discuss tried-and-true methods of packaging, as well as introduce several new technologies for meeting packaging requirements.

FACTORS AFFECTING PACKAGE CHOICE

There are many important factors to be considered when a packaging system is required. All of these factors will, to a varying extent, influence the choice of materials. Ideally, they should be communicated to the packaging supplier as early as possible in the project.

Sterilization Methods. The first factor to be considered with medical packaging materials is the sterilization method. Many times the packager is committed to a certain method because of product restrictions, process economics, or equipment availability. If end-users are locked into autoclave sterilization, then heat-resistant materials must be used. Some medical products are incompatible with specific sterilization methods. For example, one would not sterilize liquids (such as filled IV bags) with ethylene oxide (EtO), as this process requires permeable packaging materials. For products that are terminally sterilized, the packager's choices are often significantly narrowed based on the sterilization method that will be used.

Barrier Level. Another key consideration is the level of barrier required. A product often needs to be protected from oxygen, moisture vapor, or light. In addition to keeping undesirable elements from entering a package, it is often equally important to keep critical product components from migrating out of the package. Aluminum foil is an excellent barrier material and, as a rule of thumb, a foil thickness of 1 mil or greater will be essentially pinhole free. Foil composites are available for both formed and nonformed applications. Aluminum metallized films, with a very thin aluminum layer on the order of 100–200 Å, are nonformable and are used to provide a lesser barrier at a lower cost than foil.

Package Clarity. Where package clarity is required, there are many options for both formable and nonformable packages. Formable barrier materials include ethylene-vinyl alcohol (EVOH) coextrusions, Barex polyacrylonitrile, and Aclar chlorotrifluoroethylene (CTFE) composites. Nonforming clear barrier webs often incorporate various barrier coatings onto 48-gauge biaxially oriented polyester (OPET), a substrate widely used for its strength, clarity, thermal stability, and chemical

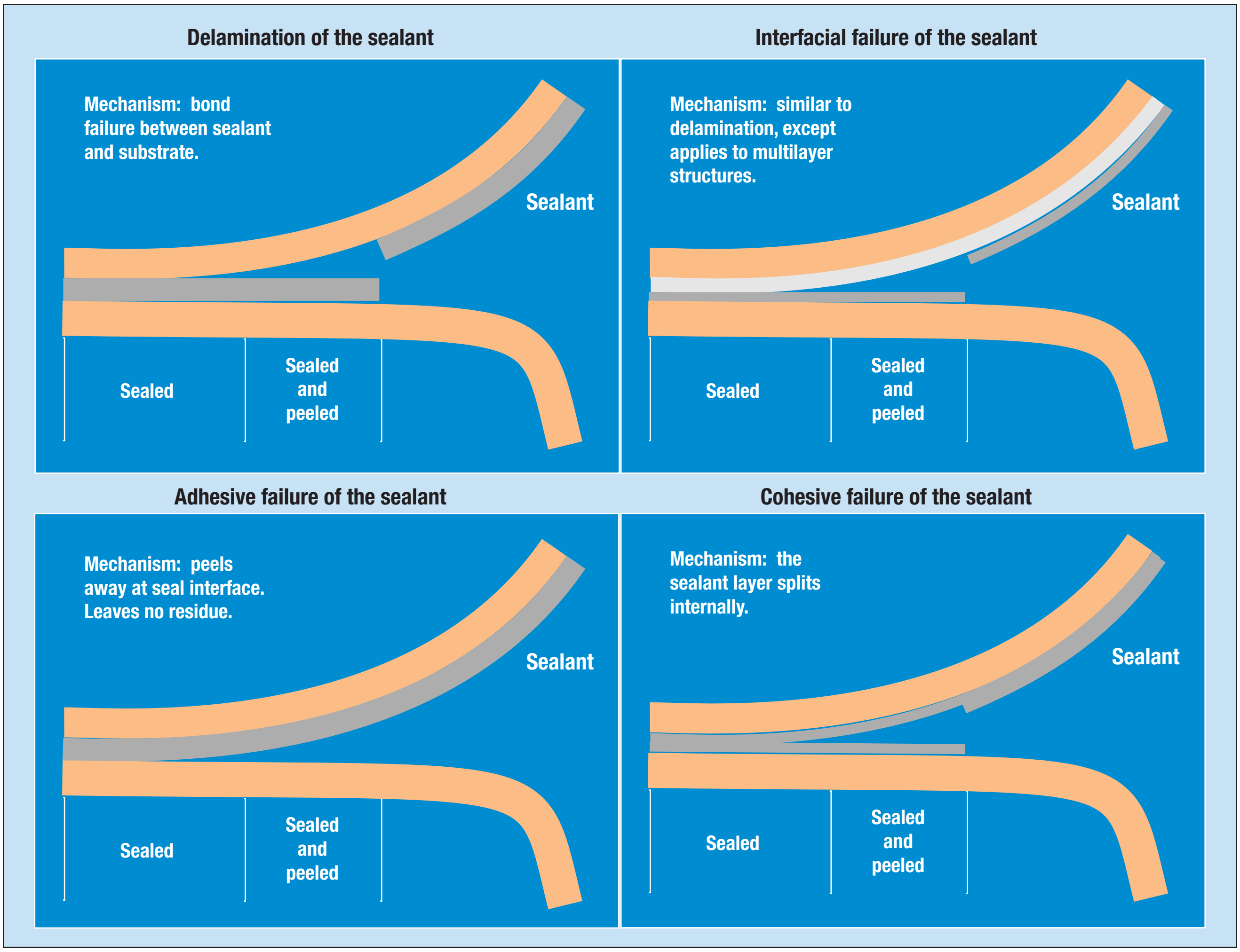

Figure 1. Common peelable sealant mechanisms.

resistance. These coatings include silicon oxides (SiO_x) or aluminum oxide (Al_2O_3), also known as glass coatings; polyvinylidene chloride (PVDC); and polyvinyl alcohol (PVOH). Table I gives an overview of the most common barrier materials used in flexible medical packaging.

Package Size. Also important is the package size and geometry. Packages can generally be classified into two main categories: flat pouches (2-D) or formed (3-D) pouches. The formed portion of a 3-D package requires the use of an extensible material—one that will retain its critical properties after the forming process. Its shape is achieved via thermoforming or pressure (cold) forming.

Chemical Resistance. Chemical resistance is important for packages that contain alcohol, iodine, aromatic, fragrances, or other active substances. Since the sealant layer is the first line of defense against aggressive chemicals, special care should go into its selection. Polyester materials form the backbone of many chemical-resistant sealants, and chemical-resistant laminating adhesives and primers may be used for these types of applications.

The five factors discussed above are among the most important when specifying packaging materials, but other considerations should include:

- Package unit cost and volume.
- Opening features—peelable seals versus weld seals.
- Type of packaging machinery—optimization of materials for certain machine types.
- Printing.
- Environmental and disposal advantages or disadvantages.
- Shelf life requirements.

FLEXIBLE PACKAGING CONSTRUCTION

With the tremendous variety of packaging materials available today, there are many possible combinations. The simplest structures may consist of just one or two layers—for example, a monolayer forming web or the OPET/polyethylene web commonly found in a basic pouch. The more complicated structures can easily exceed eight layers, including all of the components such as primers, inks, and tie layers. Flexible packaging materials for medical packaging applications incorporate one or several elements.

Heat-Stable Material. This material serves as the outer layer of a flexible packaging composite. This side of the web is typically exposed to a heat-sealing die, so good thermal stability is important. OPET is most commonly used. A suitable print surface may be needed for in-line printing applications. Oriented polypropylene (OPP) film can be used where less thermal stability can be tolerated, although not all OPP films can be used for radiation sterilization. Biaxially oriented nylon (BON) is more expensive than OPET but has greater flexibility for better stress-crack and pinhole resistance. Cast nylon film is used as the heat-stable layer in many forming applications. Paper can be used for its excellent heat resistance and print surface, but it is prone to tearing and fiber generation.

Barrier Layer. The barrier layer provides the required barrier properties. The barrier layer can consist of aluminum foil, Aclar film, a barrier resin such as EVOH, or a barrier coating such as PVOH, PVDC, vacuum metallized aluminum, or one of the glass coatings. The barrier coatings are generally applied to a heat-stable material such as OPET; this type of coated film can serve as both the barrier layer and the heat-stable material. Barex, which is an excellent oxygen barrier, is used as a film lamination as well as a rigid tray material.

Sealant Layer. The proper sealant helps ensure a hermetic package. It is the portion of the package that is in contact with the product. A sealant layer may be provided as a monolayer or coextruded film—either blown, cast, or extrusion coated. Both peelable and weld seals may be formulated from the entire range of extrudable resins: low-density polyethylene (LDPE), high-density polyethylene (HDPE), ethylene copolymers such as ethylene vinyl acetate (EVA) and ethylene methyl acrylate (EMA), other acrylate copolymers, Surlyn ionomer, polypropylene (PP), and extrudable amorphous polyesters. A weld seal is usually obtained by sealing like materials together, while the mechanisms for peelable seals involve "controlled incompatibilities" between polymer materials. Figure 1 shows some common peelable sealant mechanisms. The sealant layer can also be in the form of a solution-applied coating, typically a vinyl acetate or PP dispersion. Solution-applied coatings are losing ground in favor of film-based sealants. Because the film-based sealants provide the sealant function as well as sheer bulk, they are usually more economical.

The sterilization method is a vital factor to consider in specifying packaging for medical devices.

Adhesives, Tie Layers, Primers. These are bonding agents that are literally the glue that holds everything together. A poor choice in this area means the package seal will delaminate either immediately or, worse, upon aging. Special challenges include retort and autoclave applications, bonding of greatly dissimilar materials, and difficult-to-bond materials such as Aclar film and some PP materials.

In addition to the major components, there are various ink, overlacquer, and epoxy systems and other functional coatings that can be applied. Given the huge variety of building blocks available, one can see why it is important to ensure that the appropriate materials are selected.

PACKAGING MATERIAL SYSTEMS

As stated above, the sterilization method is a vital factor to consider in specifying packaging for medical devices, because once the sterilization method is known, the range of appropriate materials narrows. For each of the major sterilization processes, there are 2-D and 3-D packaging systems in place.

EtO Sterilization. For effective EtO sterilization the packaging material must be breathable to allow the high-humidity EtO gas mixture to infiltrate the package. A partial vacuum is drawn before and after the cycle to facilitate the movement (in and out) of the EtO and moisture vapor. If the package does not have sufficient permeability, the process will be ineffective. As stresses in the seal area are introduced due to the pressure difference between the inside and outside of the package, a seal failure phenomenon known as sterilizer creep may occur. The package must also withstand the moderately elevated process temperatures, although this is typically not a problem for most materials.

A typical 2-D breathable pouch consists of a PET/PE bottom web combined with a Tyvek or paper top web. The Tyvek or paper top web is the breathable portion, and it may be coated or uncoated. Uncoated Tyvek has a Gurley Hill porosity of about 20–25 sec/100 cm^3 air per square inch; typical coated Tyvek has a porosity of 80–100 sec/100 cm^3 air per square inch. A less-breathable coating can be applied as a patterned coating, such as a grid or dot pattern. Tyvek or paper also provides a suitable print surface and good aesthetics. Because one disadvantage to Tyvek is its expense, a great many 2-D pouch applications use a Tyvek header strip or vent, to save on material cost.

For 3-D packages used with EtO sterilization, the same breathability requirement exists as for 2-D pouches; therefore, the same breathable materials (paper or Tyvek) can be used. Instead of a flat, nonformable bottom web, some type of thermoformable web should be used. The traditional thermoforming webs of EVA/ionomer/EVA are being challenged by more cost-effective approaches, such as using linear low-density polyethylene (LLDPE) or Surlyn blends in the core, or even moving to a monolayer blend. The more costly coextruded-nylon forming webs provide outstanding toughness and impact resistance that is not easily matched by using strictly PE-based polymers and blends. To further improve pinhole and puncture resistance, multiple layers of nylon are often used. Given the wide cost range, it is important not to overdesign the package for the product.

Steam under Pressure (Breathable Autoclave). Packaging material requirements for steam sterilizing are similar to those for EtO in that the package must be breathable to allow for steam infiltration. An additional requirement is heat resistance. A typical steam autoclave cycle may be run at 121°C, but temperatures up to 140°C (284°F) may be used. For the breathable portion of the package, Tyvek—which is made of spunbonded HDPE fibers—may be used, but only under very controlled conditions where temperatures do not exceed 127°C. Many papers will withstand the process without significant loss of physical properties. A suitable heat-seal coating could be based on PP or amorphous polyester.

In-hospital autoclave sterilizers have long used steam sterilization for 2-D packages. A typical structure is an OPET/PP bottom web and a paper top web. This type of package is very low cost and may not have all the desired properties for in-hospital use such as fiber-free opening and microbial barrier.

Material Type	Material	Trade Name	Thickness (mil)	MVTR	O_2TR	Formable	Autoclaveable/ Retortable**
Clear barrier materials	CTFE	Aclar 22C	1	0.035	N/A	Yes	Yes
	CTFE	Aclar UHRx 3000	1	0.015	N/A	Yes	Yes
	CTFE	Aclar SupRx 900	1	0.019	N/A	Yes	Yes
	COC	Topas 8007	1	0.071	N/A	Yes	No
	COC	Topas 6015	1	0.11	N/A	Yes	Yes
	Liquid crystal polymer	Vectran V200P	1	0.015	N/A	Yes	Yes
	OPET		1	1.5	4.5	No	Yes
	OPP		1	0.33	N/A	No	No
	PVC		1	1.8	9.1	Yes	No
	Oriented nylon		1	9	2	No	Yes
	Cast nylon		1	19	3	Yes	Yes
	Polyacrylonitrile	Barex	1	5	1	Yes	No
	PVDC-coated PET		*	0.5	0.5	No	No
	PVOH-coated PET		*	4	0.2	No	No
	Al_2O_3-coated PET	ClearFoil M	*	0.03	0.045	No	No
	Al_2O_3-coated PET	ClearFoil M2	*	0.3	0.04	No	Yes
	SiO_x-coated PET	ClearFoil F	*	0.02	<0.003	No	No
	SiO_x-coated PET	ClearFoil A	*	0.04	0.04	No	Yes
Opaque barrier materials	Metallized PET		*	0.05	0.1	No	No
	Aluminum foil (flat)		0.035	0.02	0.03	No	Yes
	Aluminum foil (flat)		0.5	0.01	0.02	No	Yes
	Aluminum foil (flat)		1	<0.00	<0.000	Yes	Yes

* The barrier for these materials is due to the coating and is not dependent on substrate thickness.

** Provided autoclaveable adhesives/sealants are used.

Note: Thin-gauge aluminum foil may be formable but not functional due to pinholes. Generally, 1-mil or thicker foils are used for formable applications.

Table I. Common barrier materials used in flexible medical packaging.

Other, more-reliable 2-D pouches employ OPET with a peelable sealant of sufficient heat resistance, based on PP or PET chemistry, and a high-strength, medical-grade paper.

A 3-D steam-sterilizable package must be breathable and heat resistant, as well as formable. This is a tall order for most packaging materials, particularly if one desires a peelable seal as well. Nylon-, PP-, or PET-based forming webs may be used with coated paper or Tyvek top webs. Alternatively, uncoated paper or Tyvek can be used if a peelable seal layer is provided as the inner layer on the bottom forming web (a more economical scenario).

If the peel layer is part of the forming web, one should be aware that the heat from the forming process can change the nature of this layer. In the case of a peelable polyester sealant, the heat from the forming station can crystallize the sealant, rendering it nonfunctional. There are also the aesthetic issues of shrinkage or snapback with some PP and nylon forming webs when subjected to autoclave temperatures. Developing a more cost-effective, peelable package for 3-D steam sterilization remains an active development area for several converters.

Radiation Sterilization. Flexible packaging for radiation sterilization has no requirement for heat resistance (other than for the heat needed to make the seals) or breathability. Although breathability is not required to achieve sterility, it is sometimes needed to allow outgassing of odors that can develop. In these cases, a Tyvek or paper top web can be used. The main limitation is that some polymers are not suited for exposure to radiation. Materials that may be adversely affected include PP and polyvinyl chloride (PVC). Adverse effects, which can occur to a modest extent in many materials, usually involve a loss of physical properties (such as embrittlement) or a color change.

Packaging for radiation sterilization can be supplied in high-barrier or nonbarrier versions. A high-barrier package would be used where the packaged product needs to be protected from oxygen, moisture vapor, and/or light. For a barrier package, both top and bottom webs will utilize a barrier material.

For 2-D nonbarrier radiation pouches, the packaging materials can be very cost-effective. A simple PET/PE laminate can be used for both sides of the web. The PE side can be supplied to

Film Sample (4-mil except where noted)	Ultimate Tensile Strength (psi)		Elongation (%)		Elmendorf Tear (g)		Cost Rank*
	MD**	TD**	MD	TD	MD	TD	
EVA/ionomer/EVA	3300	3200	530	580	100	130	4
FlexForm B	4000	3400	800	850	500	1200	2
PE/nylon/PE***	5800	5900	460	420	110	160	3
Nylon/PE***	6200	6200	460	470	470	420	3
LLDPE	3400	2600	550	830	500	810	1

* 1=least expensive.
** MD=machine direction; TD=transverse direction.
*** 3-mil sample. Note: Differences in the amount and type of nylon used can significantly change the properties. These values represent only one version of this structure.

Table II. Flexible bottom-web comparison.

give either a peelable seal or weld seal. Prefabricated linear-tear or snap-tear bags, made from a single coextruded film, can be used. For barrier applications, one would need to incorporate aluminum foil or one of the other materials mentioned above in the discussion on barrier materials.

For 3-D radiation, a formable bottom web is used. For nonbarrier applications, the same webs used as bottom forming webs for 3-D EtO packages are employed. For barrier applications, one of the formable barrier webs, such as a coextruded film containing EVOH, an Aclar lamination, or a formable foil, can be used.

Retort Sterilization (Nonbreathable Autoclave). In some nonbreathable autoclave applications, a liquid-containing package is sterilized in a retort process. Seal integrity is extremely important in these applications because, unless the engineer has precise overpressure control, the pressure difference between the inside and outside of the package may easily result in seal failures. This is an area where very strong peelable seals are often specified. The same high heat resistance needed for breathable steam applications is also required. In general, a barrier package for this type of sterilization can use either clear barrier or foil barrier composites. Not all of the barrier materials are autoclaveable, and not all of the autoclaveable materials are thermoformable. Table I indicates which barrier materials apply for retort and autoclave sterilization.

A 2-D barrier pouch for retort or autoclave sterilization can be made from aluminum foil or from one of the nonfoil autoclaveable barrier materials. Autoclaveable clear barrier materials are often more expensive than foil; therefore, a pouch can be made of foil on one side and the clear barrier material on the other. This will suffice provided the end-user does not need clarity on both sides of the package and the packaging equipment can accommodate two different webs.

For this sterilization method, 3-D packaging usually consists of a rigid thermoformed tray and a flexible film lidstock. The lidstock can be foil based or use a nonfoil barrier material.

Other Sterilization Methods. Although the previously mentioned sterilization methods represent the major applications, other methods are well worth mentioning. Dry-heat sterilization is used for products that do not lend themselves well to other sterilization techniques, do not contain moisture, may be damaged by contact with moisture, and are stable at elevated temperatures. This technique requires a long exposure time (as long as several hours) at elevated temperatures (275°F and above). Heat resistance is the main packaging requirement. Some examples of dry-heat-sterilized products include orthopedic implants, collagen products, and surgical instruments.

Hydrogen peroxide (H_2O_2) gas plasma sterilization is drawing interest as a substitute for EtO sterilization. Developed by Advanced Sterilization Products (Irvine, CA), the Sterrad system is gaining acceptance in both institutional and industrial use. A breathable package is required for the gas to permeate the package. Although this is done in a drier and slightly cooler environment than EtO sterilization, the same types of package materials are appropriate. The only known exception is paper, which cannot be used; the cellulose fiber in paper can absorb enough H_2O_2 to make the process ineffective. Since this method is relatively new, not all materials have been thoroughly tested. One of the main benefits of this process is greatly improved cycle time; since the primary by-products are water and oxygen, there is no aeration required. This is very important to help achieve quick turnaround in clinical settings. Compared to EtO, the environmental and regulatory concerns are minimal.

Developing a more cost-effective, peelable package for 3-D steam sterilization remains an active development area.

PurePulse Technologies (San Diego) has developed PureBright broad-spectrum pulsed light (BSPL) technology, a sterilization process used primarily in applications involving blood components, vaccines, and other biopharmaceuticals, as well as dry surfaces. Highly intense, short flashes of broad-spectrum light (ultraviolet, visible, and infrared) are used to rapidly deactivate organisms without the use of intense heat, hazardous chemicals, or by-product generation. Packaging materials compatible with this process will transmit light over the broad spectrum employed. LLDPE, LDPE, nylon, Aclar, HDPE, and PP have all been used. Polystyrene, PET, and glass are all very

Sealant	APET	CPET	PETG	Polycarbonate	PVC	Barex	Itself
Allegro P	P	P	P	P	P	P	—
Allegro O	P	P	P	P	P	P	—
Forté P	W	W	W	W	—	—	W
Forté PI	W	—	W	—	—	—	W
P = Peelable W = Weld							

Table III. Types of seals achieved when extrusion-coated polyester sealants are used with various materials.

clear to the eye, and one might expect these materials to work well. In reality, these materials do not transmit light in the ultraviolet region of the spectrum and, therefore, are not suitable for use with this method. Package geometry should not allow any shadowing on the product or the light exposure may not be sufficient.

NEW MATERIALS

Polymer Blends for Thermoforming Webs. For years, the standard thermoformable bottom web used in the United States has been an EVA/ionomer/EVA coextrusion. More recently, PE/nylon/PE and nylon/PE structures—always popular in Europe—have made the transition from the food industry to the medical industry. With the drive to reduce costs, film manufacturers have been challenged to find more competitive alternatives to the old standards.

The availability of new high-performance packaging resins such as metallocenes, ultra-low-density polyethylene (ULDPE), and very-low-density polyethylene (VLDPE) has made the use of polymer blends in thermoforming applications a viable alternative. Costs are reduced as more-expensive materials, such as ionomers, are replaced with less-expensive resins. As many of these blends can be produced on monofilm lines, which are often fully depreciated and underutilized, manufacturing costs are further reduced.

Lower cost need not be equated with reduced performance. Table II provides a comparison of performance and cost for several blends and the traditional thermoformable bottom webs. For less-demanding applications, lower-performance blends of LDPE and PE copolymers can result in significant cost savings, and may be perfectly suitable for soft goods packages with shallow draws. Special care should be taken when evaluating these packages over the life cycle of the product.

Sealants for Uncoated Paper and Tyvek. In the drive to reduce costs, there has been a significant focus on developing high-performance sealants for use with uncoated paper and uncoated Tyvek. A successful sealant needs to provide the look and feel of a seal made to coated paper or Tyvek, prevent fiber tear from occurring when the seal is opened, and provide an impressive total-package cost savings.

The sealant technology that has been most successful is based on a cohesive peel mechanism. Rather than adhesively peeling from the paper or Tyvek and risking fiber tear, the sealant is designed to fail internally, leaving a small amount of sealant on the paper or Tyvek (see Figure 2). Core-Peel, from Rexam Medical Packaging (Mundelein, IL), and Allegro T from Rollprint Packaging Products (Addison, IL) use this approach. By marrying this sealant technology with bottom forming webs, the transition from a 2-D pouch to a 3-D package can be accomplished.

The choice of paper is extremely critical and will determine the success of the program. The use of uncoated paper provides some unique challenges. Because coated paper has a better microbial barrier than the same paper without coating, many papers used for coated applications are not appropriate for uncoated use from a microbial-barrier standpoint. In addition to a microbial barrier, the paper should provide durability, be sufficiently porous, and have high internal bond to prevent fiber tear. Kimberly-Clark (Dallas) recently introduced Impervon paper, which has been designed specifically to be used as an uncoated paper for medical applications.

Polyester sealants are superior when it comes to containing hard-to-hold chemicals.

Chemical Resistance. One of the most exciting developments in chemical resistance has been the introduction of extrusion-coated amorphous polyester sealants. The sealant technology has long been available in film form; however, its relatively high price and various performance issues have limited the film's market to specialty applications.

Figure 2. Peelable pouch for EtO and gamma sterilization using tamper-evident seal technology.

Polyester sealants are extremely clean. They are very unlikely to leach from the packaging into the product or to scalp from the product. As a result, they are excellent for holding products where there may be a very small amount of an active ingredient present.

Polyester sealants are superior when it comes to containing hard-to-hold chemicals. They can also protect other, more-vulnerable materials. For example, aluminum foil will discolor and pinhole when exposed to oxidizing agents such as

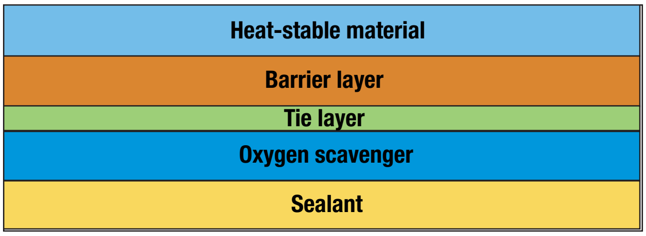

Figure 3. Schematic of a typical O_2 scavenger material.

iodine. A polyester sealant will serve the dual purpose of protecting the aluminum foil while also providing the desired seal properties.

Extrusion-coated polyester sealants are available to provide both peelable and weld seals to a variety of materials, as illustrated in Table III. In many applications, a polyester barrier is needed to protect a substrate—such as aluminum foil—from the product, but a polyolefin sealant is desired. Advances in extrusion coating technology now allow polyester and polyolefin to be coextrusion coated onto the foil (or other substrate), economically reaping the benefits of both polymer systems.

High-Heat Resistance. Extrusion-coated amorphous polyesters have also widened the material choices available for applications requiring high-heat resistance. Historically, polypropylene sealants, either as films or coatings, have been used for autoclave applications. The sealants are designed to seal to themselves or other polypropylenes (e.g., rigid polypropylene trays).

Extrusion-coated polyester sealants maintain stability at higher temperatures than either PP or HDPE. This makes them ideal for autoclave applications and makes dry-heat sterilization a realistic option. Melt temperatures are 266°F for HDPE, 329°F for cast PP, and 469°F for APET sealant. (Temperatures for dry-heat sterilization can range from 275° to 350°F.) They can be sealed to themselves or to other polyesters. For lidding applications, the use of CPET, APET, or polycarbonate trays becomes an option.

Oxygen Scavengers. Oxygen scavengers are ideal for applications requiring extremely low-oxygen environments. The scavenger absorbs oxygen remaining in the package headspace, as well as oxygen ingress through the packaging material. Oxygen absorption occurs through an oxidation reaction. Because the amount of oxygen that can be absorbed in the reaction is finite, a passive oxygen barrier (e.g., foil) must be used. In addition, gas flushing or vacuum packaging is recommended. The oxygen scavenger is part of a multilayer structure and is generally buried between the passive barrier layer and the sealant layer (see Figure 3).

Ferric (iron-based) compositions have been the traditional oxygen scavenger. These systems are moisture activated; the oxygen-absorbing capacity is highly dependent on the relative humidity (RH) level. At an RH of 40% or less, these systems are not activated. This precludes their use with moisture-sensitive or dry product applications. To preserve the oxygen-absorbing capacity, resins and films must be stored at low RH prior to use.

Recognizing that many polymers oxidize and therefore could be used as scavengers, researchers have been concentrating on identifying polymers that do not degrade during the oxidation process. Degradation is undesirable as the degradation products could potentially migrate into the product. Chevron Phillips (San Francisco) has developed an oxygen-scavenging polymer (OSP) system that is stable and has controlled activation. The system consists of an oxidizable polymer, a transition metal catalyst, and a photoinitiator. Films made with the OSP system remain in a nonscavenging state until triggered by exposure to UV light—typically during the filling process.

With the use of appropriate barrier materials and filling techniques, oxygen-scavenging polymers can provide a virtually oxygen-free environment for products.

Moisture Barriers. CTFE films have long set the standard for clear, high-moisture-barrier films. The fact that they can be thermoformed makes them a distinctive packaging product. This impressive performance comes at a significant economic price, however.

The introduction of cyclic olefin copolymers (COCs) provides a thermoformable alternative to CTFE. Although their moisture barrier capability is not quite as good as that of CTFE, they cost much less. COCs thermoform at relatively low temperatures and have rapid cycle times, making them very attractive for clear forming applications requiring a moderate moisture barrier.

The fact that CTFE films can be thermoformed makes them a distinctive packaging product.

In nonthermoforming applications, such as pouches and bags, COC/polyethylene blends can dramatically increase film stiffness and improve the moisture barrier without affecting clarity and oxygen permeation.

Liquid crystal polymers (LCPs) offer another new moisture barrier option for multilayer packaging. They can be designed to be coextruded with polyolefins. LCPs are highly inert, offer excellent thermal stability and chemical resistance, and also provide good moisture, oxygen, CO_2, and aroma barriers.

The excellent performance and relatively low cost of aluminum oxide (Al_2O_3)–coated polyesters make them a very popular barrier choice. Because of the cost considerations, they are often considered as a replacement for silicon oxide (SiO_x) coated polyester. Al_2O_3-coated polyesters offer a range of barrier and price options. They are thermally stable, offer excellent clarity, and can be combined with virtually any sealant option. In addition, some grades are autoclaveable.

CONCLUSION

With myriad options available today in the field of flexible packaging, the device producer has several alternatives for meeting product packaging requirements. Traditional packaging materials are being replaced by more cost-effective structures, and many new materials are just entering the arena. These expanded choices will help to optimize package performance, resulting in cost savings for the packager. In today's competitive climate, few can afford to overengineer (or underengineer) their packaging systems. ■

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ROLLPRINT PACKAGING PRODUCTS, INC.

320 S. Stewart Avenue
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Toll Free: 800.276.7629
Fax: 630.628.8510

www.rollprint.com