Exploring the Benefits of Polyurethane Thin-film Welding for Medical Device Applications

POLYZEN

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Thermoplastics have been used in flexible medical product applications since the 1960s, when plasticized polyvinyl chloride (PVC) blood storage bags replaced glass bottles.[1] In the 1970s, PVC became the material of choice for Band-Aids®, and a decade later the use of polymeric film patches in surgical draping became popular, replacing latex films. Over time, the use of organ bags, drug-delivery patches, and breathable films for wound care increased dramatically, resulting in a demand for films in the medical industry. Today, a wide range of applications require the use of thermoplastics, including devices with critical requirements around biocompatibility, hemocompatibility, durability, and strength. Such applications range from total artificial hearts to intragastric balloons, amongst many others.

Nearly all thermoplastics can be used in film form as thin, soft, flexible, elastomeric materials that can be folded or creased without damage. In selecting films for medical devices, designers must consider a variety of factors, including cost, biocompatibility, sterilizability, mechanical toughness, elasticity, optical clarity, leachability, barrier properties, drug interaction, and sealing and assembly characteristics.

Health and environmental concerns about PVC and latex films have prompted manufacturers to seek out new applications for materials such as polyurethane. To make effective use of this material, however, designers must understand how it responds to various bonding processes.

WELDABILITY OF THERMOPLASTICS

Films most commonly used in the medical industry include high- and low-density polyethylene and polypropylenes from the polyolefin family, plasticized PVC, polyurethane elastomers, and breathable

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specialty films such as polyester. Designers need a clear understanding not only of the properties of the material, but also how it will be impacted by a particular welding process.

The weldability of plastics is affected by various factors, including:

- type of polymer;
- resin grade;
- presence of plasticizers, lubricants, and other additives;
- and moisture content.

Thermal properties, molecular characteristics, and crystallinity of a polymer affect processing and film properties; additives influence extrusion and orientation processes and improve film properties; and reductions in the thickness of a film can lower costs and increase the area obtained from a given weight of polymer yield per square meter.[2]

Amorphous polymers respond better to welding than crystalline polymers because they soften, melt, and resolidify gradually. However, some amorphous resins with high melting points, such as polycarbonate and polysulfones, are difficult to weld.[3] Crystalline polymers, which have high, more defined melting points, tend to melt and resolidify quickly, making them challenging to weld. Crystalline polymers include polyethylene, polypropylene, nylon, thermoplastic polyesters, acetal, and polyphenylene sulfide.

Thermoplastic polyurethane, an aromatic or aliphatic polymer, is well-suited for use in flexible medical applications. Polyurethane films offer some important advantages over other films, including PVC. They have similar welding characteristics to PVC, provide strength equal to PVC in a thinner film, contain no plasticizers, and are sterilizable by either ethylene oxide (EtO) or gamma radiation. They also have good alcohol resistance. Polyurethane films can be readily sealed using radio frequency (RF) welding techniques.

FILM-JOINING METHODS

Welding processes commonly used in assembling medical devices from thermoplastic films include RF welding, also known as dielectric sealing; ultrasonic welding; direct thermal sealing; induction welding or sealing, and solvent bonding (see Table I). Selecting the best process for bonding thin-film materials in the assembly of medical products involves several considerations. The material itself is the primary factor. Size of the product, volume, process capability, cycle time, and cost are other critical variables.

In each welding process, controlled heat is applied to the materials, causing the plastic to melt in a narrow zone at the joint interface. Pressure is applied and, once the heat is cut off, the material cools and resolidifies, forming a weld bond. The amount of compression used is important,

Process	Mechanism	Special Features	Suitable Materials
Flame bonding	Natural gas flame	Continuous web application	PVC-to-foam lamination
Hot air gun	Hot air or nitrogen	Plastic welding rods	Low-melting plastic, PE
Hot knife welding	Heat from metal surface	Bond in one plane	Thermoplastic rubbers
Hot plate welding	Hot tool/die	Draft angle of bar	High-temperature plastics
Induction/impulse	Resistance wire	Straight line seal	Olefins, low-temperature films
Dielectric – RF	Loss in alternative electrostatic field	Quick bonding	Polar or amorphous elastomer
Ultrasonic welding	High-frequency compressive loading	Sonic conductor	Rigid plastics
Solvent bonding	Material swell/dissolve	Chemical fusion	Amorphous resin

Table I: Fusion welding processes. Adapted from Encyclopedia of Polymer Science and Engineering (New York: Wiley).

since too little or too much can result in a weak seal. A smooth, uniform bead along the weld line is ideal.

RF Welding. RF welding, a form of dielectric heating, is one of the most widely used methods for assembling medical devices. The process offers:

- consistent quality;
- thin, strong weld lines;
- short sealing cycles for high output;
- minimal thermal distortion of the film or substrate;
- and the ability to produce weld-edge tear seals.

Advantages
The most important advantage of the RF process is extremely thin weld seams. Impulse welding and hot-bar sealing produce a seal area that is about 1/8 in. wide, which is too wide for some medical applications. For applications such as containers, the width of the seam is not significant, but for implantable medical devices, a thinner seam is preferred.

Interactivity with electricity and radiation
The materials joined by RF welding must be poor conductors of electricity, since a good conductor would act as a short circuit, weakening the field near the conductor. Polyethylene, polypropylene, polystyrene, silicone, and rubber, for example, are not responsive to the RF welding process. Polymers with strong dipoles respond best to RF welding.

Material	Loss Index	"Response (G=good, F=fair, P=poor, N=none)"
ABS polymers	0.025	F–P
Acetal resin	0.025	F–P
Cellulose acetate	0.15	F
DAP	0.04	F
Epoxy	0.12	F
Melamine	0.2	G
Phenal formaldehyde	0.2	G
Polyamide	0.16	F
Polycarbonate	0.03	F–P
PVDF	0.04	F
Polyester	0.05	F
Polyethylene	0.0008	N
Polyimide	0.013	P
PMMA	0.09	F
Polypropylene	0.001	N
Polystyrene	0.001	N
PTFE	0.0004	N
FEP	0.001	P
PVDF	0.05	F
PU film/foam	0.4	G
PVC film, flexible	0.4	G
TPE	0.13	F
Silicone	0.009	P–N
Urea formaldehyde	0.2	G

Table II. Response of polymers to dielectric heating. Adapted from J.D. Ferry, Viscoelastic Properties of Polymers (New York:Wiley, 1970), and S. Saito and T. Narajiman Journal of Applied Polymer Science 2:1959, 93.

The RF process generates radio-wave power, which produces enough heat to melt plastic materials and produce a free exchange of molecules, thereby bonding materials. Alternating current (AC) power is converted to a high voltage direct current (DC), which an oscillator or resonator outputs as an alternating current. Although dielectric heating can be performed at frequencies ranging from 10 to 100 MHz, the radio frequency most commonly used in the United States is 27.12 MHz.

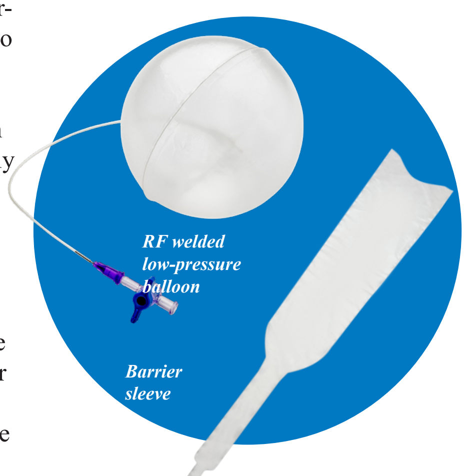
An interchangeable electrode, or die, machined in the shape of the part to be welded, is used to apply power to the workpiece. Such electrodes are commonly made of brass since the metal transfers heat evenly. The electrode is pressed against the part, and a high intensity alternating field is directed through the material. The degree of polarization and the energy required to achieve it control the loss factor or dissipation factor of a material. A material that is readily polarized by a small electric field has a high loss factor and is easy to heat (see Table II). If the polarizing field changes direction at a high frequency, a considerable amount of energy, in the form of heat, can be imparted to each molecule of the material.

During the RF process, molecules within the material are agitated and move rapidly in a lateral direction, trying to align with the changing electric field. As a result, heat is generated within the material, allowing for excellent uniformity and remarkable speed of heating. The heat produced is highest at the interface of the two components being joined. With other methods, such as thermal sealing and impulse welding, the outside layers of the plastic that touch the dies are the hottest areas, which can result in degradation of film surfaces.

When the power to the RF-energy generator is shut off, the melted plastic resolidifies, resulting in a uniform weld that is as strong or stronger than the materials being bonded together. The entire process can take from a fraction of a second to several seconds, depending on the polymer, film thickness, and size of the welding zone.

Tooling. Tooling for the RF welding process consists of an upper die mounted to an aluminum tool and jig plate and a bottom die or nest, typically made of aluminum. However, any metal that conducts electricity will work. Tooling with rounded weld lines provides a stronger seal than straight lines. Sharp edges and corners are not desirable since voltage rises when it is applied to corners and sharp edges. This can increase the likelihood of arcing, which can damage the film as well as the die.

Applications. The RF welding process is advantageous for the development of barrier sleeves for infection control or specialty low- pressure balloons for applications within therapeutic, diagnostic, or drug-delivery medical devices. RF welding is desirable in these cases, enabling the production of seams that are as strong as or stronger than the actual film itself, resulting in resilient performance. The applications of thin-film welding are innumerable and are optimized by the efficiency and continuity performance of the process. Any thermoplastic elastomer material can be welded to form a weld seam to produce various medical devices including barrier products, multi-layer articulated balloons, gloves, condoms, inflatable catheter balloon cuffs, bladders, specialty bags, and bioreactor bag liners.



Ultrasonic Welding. Ultrasonic welding directs ultrasonic vibratory energy through thermoplastic workpieces, causing them to melt at the interface and form a bond. Electrical energy is transformed into high-frequency (20 to 40 kHz) vibrations, which are directed into the workpieces in a holding fixture through an ultrasonic horn. The most important variable affecting the ultrasonic process is vibrational amplitude, the peak-to-peak displacement – or excursion – of the horn. Controllers can improve weld integrity by varying the amplitude to meet the changing requirements during each cycle. Once melted, the plastic is pressed together and held until cool.

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The ultrasonic energy requirements of thermoplastic materials are determined primarily by the melt temperature, modulus of elasticity, and structure of the material. Soft plastics with a low modulus of elasticity are difficult to weld with this process because they attenuate the ultrasonic vibrations. Rigid plastics are more responsive to the vibratory energy, and typically melt in less than two seconds, producing a strong, uniform molecular bond.

Direct Thermal Sealing. Direct thermal sealing methods are well suited for joining soft plastics such as polypropylene, polyethylene, and thermoplastic polyimides. In hot-tool welding, one or more electrically heated platens or bars are pressed against the surfaces of the films until they melt and bond together at the point of contact. A nonstick coating on the tool facilitates its removal.

Temperature, time, and pressure are the primary variables. Platens for temperatures up to 500°F are made of aluminum. For higher temperatures, bronze and steel are used. Cycle time is typically less than 20 seconds. Using heated platens on each side of the parts can reduce the welding time of a thermoplastic to 1–3 seconds. Since heat must be conducted to the joint interface, the thickness of the materials being welded is also an important consideration. Thickness is generally limited to about 1 mm.

Impulse Sealing. Impulse sealing is an advanced form of hot-tool welding, in which the heating and cooling cycles are controlled while the joint is held under pressure. Impulse-type sealers use a metal wire or bar that is heated intermittently to avoid overheating the plastic material. Hot-bar and impulse welding processes are commonly used in the packaging industry to seal plastic bags and join thermoplastic films of 0.5 mm or less.

Hot-Plate Welding. Hot-plate welding is another variation of direct thermal sealing. The layers of thermoplastic film to be joined are pressed against the sides of a heated platen, which is removed when the plastic melts. The joined film is pressed together and held at the interface until the material cools, forming a molecular bond. Most thin thermoplastic films can be welded with this process.

Induction Welding. A form of electromagnetic heating, induction welding uses a metal element in the shape of the weld line to bond thermoplastic materials. The metal vibrates rapidly when subjected to a magnetic field, producing heat. When film is pressed against it, the molecules in the plastic melt and fuse together.

Solvent Bonding. In this method, a solvent, such as methylene chloride, is applied along the joint interface. The thermoplastic films are then held together in a fixture. As the solvent evaporates, polymer chains move about freely and become entangled with other chains. The result is a solid mass of entangled polymer chains that produce a weld. The main limitation of this technique is in the handling of the solvent. The pressure and time required for the process depends on the thermoplastic material, the solvent, and the joint design.[4] Amorphous thermoplastics are more suitable for the process than crystalline materials.

HARNESS THE BENEFITS OF THIN-WELD POLYURETHANE

The very thin seams that can be created by RF welding polyurethane film have opened up a whole new area of applications of the material for medical products. It is possible to produce multipart welded devices that look, feel, and perform like seamless products. Thin polyurethane films have begun replacing PVC and latex in many medical products and will continue to do so as the medical industry moves towards new solutions.

Consider partnering with an experienced polymer-based device and component supplier to ensure your medical innovation leverages the most appropriate thin-film welding techniques to ultimately impact patient care.

To explore polymer-based medical device and component solutions, visit www.polyzen.com.

REFERENCES

1. Cody, T. "Innovating for Health" (Deerfield, IL: Baxter International, 1994).
2. "Films, Manufacture." *Encyclopedia of Polymer Science and Engineering* (New York: Wiley).
3. *SPI Plastics Engineering Handbook, Joining and Assembling Plastics* (Society of the Plastics Industry), 730.
4. "Solvent Bonding, Designing for Machining and Assembly Bonding" (Midland, MI: Dow Chemical, 2002).