Stevens Urethane Film, Sheet &Tubing for Medical Applications

The high-performance material for the most critical of today's "can't fail" applications.

Stevens Urethanes offer a unique combination of superior performance characteristics proven in a broad range of "can't fail" medical applications.

Of all the thermoplastic materials available for use in medical products, durability, purity, fabricability, and ease of disposal make urethane particularly attractive.

JPS Elastomerics Corp., manufacturer of Stevens Urethane film, sheet and tubing, will assist medical product designers in taking advantage of this unique and versatile material.

Stevens Urethane film, sheet and tubing, truly today's high technology material, is already the specified material of choice in many sophisticated medical treatment products and equipment. A unique combination of critical performance characteristics has put Stevens Urethane in front of other thermoplastic materials when it comes to designing devices on which people's lives depend. With a molecular structure composed of four of the world's most common elements (carbon, hydrogen, oxygen, and nitrogen) urethane compounds possess a combination of properties which are not available in any other thermoplastic material. Most often, when two or more of these performance characteristics are combined, urethane will outperform any other material or even combinations of materials, cost effectively.

Stevens polyurethane has already been proven time and time again in demanding medical applications.

Urethane film and sheet outperform traditional materials such as vinyl in many medical applications and, if you compare the characteristics of both materials, it is clear why, in many instances, urethane has become the material of choice, particularly for

critical, "can't fail" medical applications. Urethane is substantially stronger than vinyl when samples of equal thickness and durometer are compared. Urethane is extremely resistant to deterioration from skin oils which makes it particularly advantageous in applications requiring skin contact, and urethane also offers a softer "hand" or non-plastic, comfortable feel, even at low temperatures. Urethane has the unique ability to remain flexible even in extremely cold temperatures.

The reliability and versatility of urethane film, sheet and tubing has already been proven in the following medical applications:

- Invasive surgical products
- Drug delivery systems
- Healthcare mattresses
- Medical anti-shock trousers (MAST)
- Medical camera drapes
- Orthopedic cold packs
- Air bladder immobilization devices
- Breast prosthesis
- Diagnostic kits
- Pressure infuser cuffs
- Wheelchair cushions
- Blood bags
- Wound care products
- Orthopedic gel shoe insoles
- Orthodontic bands
- Compression dressings
- Face/nasal mask accessories
- Dental equipment
- Transdermal patches
- Surgical drapes

Vinyls, on the other hand, tend to become brittle, stiff and, under extreme conditions, may even crack, which is unacceptable in applications where the product may be stored in environments subject to a wide variation in ambient temperatures, such as in an ambulance or at a remote first aid station. Finally, there is the long-standing industry problem of vinyl plasticizers and other chemicals leaching out of PVC formulations, often leading to degradation, and possible application contamination problems.

The ability of Stevens Urethane film and sheet to elongate and return to its original dimension without significant "loss of memory" (as well as its flex-fatigue resistance) makes it the ideal material for bladders and other components subjected to a range of physical and temperature stresses.

Stevens Urethane film, sheet, and tubing also exhibit exceptional abrasion resistance which provides greater reliability and longer life in applications where the material may be fabricated with other materials such as wovens, or in the case of tubing used to connect movable components in medical devices. Urethane tubing also exhibits excellent flexibility and kink resistance.

Stevens Urethane film, the key component in a new Topical Cooling Device

A new Topical Cooling Device fabricated from Stevens Urethane film has become a key element in myocardial preservation in open heart surgery, replacing ice slush or cold water. The TCD™, manufactured by COBE Cardiovascular, Inc., consists of a flexible, foam-insulated urethane pad that is wrapped around the heart during the entire procedure. A cooled saline solution is pumped in a closed loop through the device. This allows for maximum cooling of the heart, rather than the surgeon's hand or fingers which often occurred when using traditional cooling methods. Urethane was specified rather than PVC for its ability to remain flexible over a wide temperature range as well as its superior heat transfer properties.

Durability and fabricability are the keys to designing effective pressure infuser bags

Pressure infuser bags, used to administer intravenous fluids under pressure at any angle to patients in pre-hospital or emergency room settings, use Stevens Urethane film laminated to fabric and sealed, using a radio-frequency technique. The durability of urethane is the key to performance in this "can't fail" medical application.

JPS Elastomerics Urethanes are easy to work with.

Another characteristic that makes urethane particularly attractive to medical and bio-engineer designers is its fabricability. Urethane film and sheet can be cut, sewn, adhesive bonded and heat laminated to any number of substrates. It can be vacuum formed, radio frequency (RF) sealed or thermally bonded to itself or other materials. It can also be fabricated together with various types of urethane tubing to provide the benefits of urethane to the entire product system, such as linked bladder applications.

Polyurethanes give the designer latitude when harsh chemical and environmental exposure is involved.

Depending on the formulation selected, urethanes can offer excellent resistance to a wide range of hydrocarbons, chemicals, ozone, fungus, moisture, and sterilant gases such as ethylene oxide.

JPS Elastomerics will work closely with you, during the critical initial product design stage, to help establish the ideal specification.

Our production people, chemists,quality control personnel, and sales staff have worked with design engineers and specifiers to bring real value and workable solutions to today's medical applications, and are ready to help you.

Many projects begin with a phone call. On a one-to-one basis, our professional staff will ask the right questions to help you determine if urethane film or sheet is suitable for your application.

Does your application require abrasion resistance? Or, perhaps the ability to withstand moisture, oils, ozone, or continuous flexing even at low temperatures? Must it be strong, yet have the ability to elongate several times its original length? Is it required to maintain chemical and structural stability with no additives such as plasticizers that can migrate out to weaken the original structure or contaminate the end-product's environment? What about surface characteristics—does your application require a specific durometer or "feel"? Are there special requirements necessary to fabricate the product?

Generally, if two or more of these characteristics are required, Stevens Urethane will be a desirable material solution from a performance and economic standpoint. Based on years of experience, we can help you make the right product choice for your tough application problems.

No other thermoplastic material has the combination of characteristics and fabricability of urethane film, sheet and tubing.

Stevens polyurethane film, sheet and tubing combine the best properties of rubber and plastic, without the weaknesses inherent in plasticized vinyl products. In comparison to alternative materials, urethanes exhibit very favorable characteristics advantageous to medical applications. These include:

Durometer. Urethane film and sheet can be produced in a range of durometers (70A-55D) from relatively stiff to flexible configurations with an extremely soft, nonplastic feel or "hand."

A comparison of Stevens Polyurethane film vs. other typical flexible materials.

Key E = Excellent G = Good F = Fair P = Poor	Stevens Thermoplastic Polyurethane film	Flexible PVC	Natural Rubber	Nitrile Rubber
Hardness (Shore A)	75-95A	60-95A	30-95A	40-95A
Specific gravity	1.12-1.21	1.12-1.5	.93-1.5	.99-1.4
Elongation %	350-800	200-400	100-800	100-700
Tear strength, #/in (Graves)	400-800	100-400	100-400	100-400
Low temperature flexibility	G-E	G	E	G
Migration	E	P-G	F-G	F-G
Flex strength	E	F	G	G
Abrasion resistance	E	F	G	G
UV resistance	F-G	G-E	P-F	F
Ozone resistance	E	E	P	F
Moisture resistance	P-E	G	G	G

The values listed are generalizations and may not represent all polymer and compound variations.

Urethanes also maintain superior flexibility over a wide durometer range at lower temperatures than other plastics.

Tensile strength and elongation. The combination of these characteristics provides great design latitude for products subjected to a range of physical stress. Urethane film and sheet can elongate and return to their original dimension without significant loss of "memory." A tensile strength range from 6,000 to 10,000 psi assures reliability and durability over the lifespan of the end product. Because urethanes are "tougher," they can be used in thinner gauges without sacrificing performance, when compared to vinyl.

Abrasion resistance. Stevens polyurethane film provides excellent abrasion resistance. Urethanes excel as a tough outer protective "skin" for laminates, or as a thick, strong seat cushion film.

Chemical resistance. Excellent resistance to hydrocarbons, chemicals, ozone, fungus, and moisture. Specify either polyether or polyester urethanes for specific characteristics that provide durability and long life to products that must survive and perform in

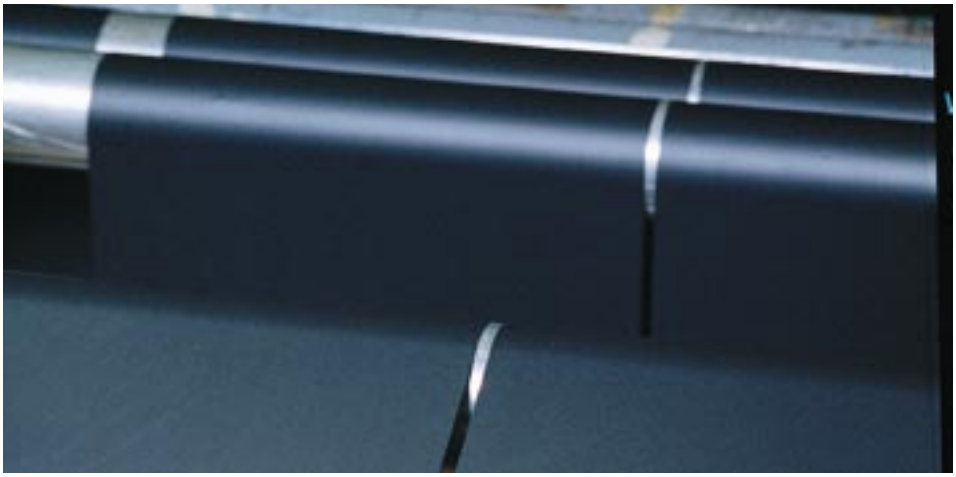
Strength and flexibility make compression dressings work

Compression dressings allow ice water to be pumped to the body injury location to minimize hemathrosis and swelling. Stevens Urethane film laminated to fabric provides the strength and flexibility at low temperatures that make this therapy work effectively. Manufacturing costs are reduced because no additional stitching or separate bladders are required.

Polyurethane MAST pants remain flexible even after long storage in the ambulance

Medical Anti-Shock Trousers made from radio-frequency-sealed urethane film are used to stabilize accident victims. Stevens Urethane remains flexible in temperatures as low as -65°F, is impervious to chemicals and other fluids often present at an accident scene, and has a long shelf life. The transparent urethane also allows continuous visual inspection of injuries.

harsh medical environments. Urethane may be sterilized with ethylene oxide without yellowing, and with gamma sterilization in cases where a limited amount of yellowing is acceptable.



Size. Stevens Urethane film and sheet are available in thicknesses from .001" to .125", in widths from 5" and up, and in a variety of colors, opacities and surface textures. Stevens Urethane tubing is available in ID sizes from 1/16" to 1-1/4", OD sizes from 1/8" to 1-1/2" with wall thicknesses ranging from 1/32" to 1/8", and is available in a variety of colors and opacities. JPS Plurotubing™ consists of two or more tubes, of variable sizes and colors, bonded into a single multiple unit, and is designed for coding purposes, or tracking fluids between components.

Selecting the proper grade. There are three types of Stevens Urethane widely used in medical applications: MP-1880, MP-1882, and MP-1890. Some grades of Stevens Urethanes are manufactured with resins listed by the National Sanitation Foundation (NSF) as meeting the requirements of Standard 61. Other grades are made with ingredients which conform to the requirements of sections of the Food and Drug Administration (FDA) 21 CFR code for certain food contact applications also applicable to medical use. Others include candidate materials for USP Class VI classification, and lot-traceable versions. JPS can even help you with FDA 510K filings.

Some design criteria may require flame resistant and/or breathable materials. JPS can help you define performance parameters, verify material selection, and implement your design. For the specific grade best suited for your application, please contact Stevens for applications assistance. The following are general specifications for the three most specified grades of Stevens Urethane:

MP-1880 A general purpose 87 Shore A polyurethane used for many broad applications.

MP-1882 A softer, more pliable polyether urethane grade that easily conforms to shapes and contours.

MP-1890 Designed for more severe applications, this high-performance polyether urethane grade offers greater temperature and puncture resistance than the softer grades.

Other benefits make Stevens Urethane the material of choice.

Stevens Urethane film can be produced in a range of colors, opacities, and surface finishes for the look and feel your application demands. It may also be printed or silkscreened. This design versatility can translate to solutions for your high-performance applications.

Another important consideration for medical applications is that Stevens Urethane is more environmentally friendly than vinyl and other films. Many manufacturers of disposable products have changed to urethane because of environmental problems resulting from the toxic by-products generated when incinerating disposable products fabricated from PVC.

Durable polyurethane helps get therapeutic cooling where it's needed

A composite of fabric and polyurethane film which is radio-frequency-sealed into "pockets" is the key to effective ergonomic cold packs designed to perfectly fit specific areas of the body. The Stevens polyurethane allows the pack to be subjected to long periods in a freezer, while maintaining strength to contain the gelatinous filler and the flexibility to remain comfortable while the pack is being worn. Unlike vinyl, the polyurethane won't crack or break down over the life of the product.

As applications become more and more demanding, and as the requirement for greater reliability and durability intensifies, more design engineers than ever before are turning to Stevens Urethane as the best solution for their critical applications. See how it can work for you.

Product Features of Stevens Urethane

	MP-1880	MP-1882	MP-1890
Tensile Properties (D638)			
Modulus @ 100% strain psi	1000	800	1500
Modulus @ 300% strain psi	2000	1100	3000
Modulus at break psi	7000	6000	8000
Modulus of elasticity up to 10% strain psi	35	25	50
Elongation @ break,%	450	550	400
Set @ break, %	35	40	25
Tear Properties Die C, D624, pli	400	375	500
Abrasion Resistance Mg. weight loss per 1000 cycles, 1000 gm. load, H18, C501, mg.	30	100	25
Maximum Service Temperatures Continuous, °F	-60 to 200	-65 to175	-60 to 225
Durometer (D2240)	87A	82A	90A
Thermal Properties: Melting point range, °F	350 to 390	290 to 330	380 to 420
Specific Gravity (D792)	1.12	1.14	1.14
Yield Factors Square feet/ pound /ml thickness	171.8	168.8	168.8
Humid Aging Resistance 90% relative humidity at 160°F / 70°C	Excellent	Excellent	Excellent

STEVENS *Urethane*

Design the reliability and versatility of Stevens Urethane into your medical devices, appliances or equipment.

Please write or call for your free Polyurethane Film Sample Kit. It contains a representative sampling of several types of Stevens Urethane Film and Sheet as well as basic technical information. Stevens application specialists are available to help solve demanding medical design applications, or improve existing designs, with urethane.

Urethane tubing, cord, and profile products

Stevens also makes a line of urethane tubing with several configurations, diameters, wall thicknesses and colors, from single tubes to our Plurotubing, which is composed of several lengths of the same or different-sized urethane tubing thermally bonded together. Custom cord and profile products are also available.

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