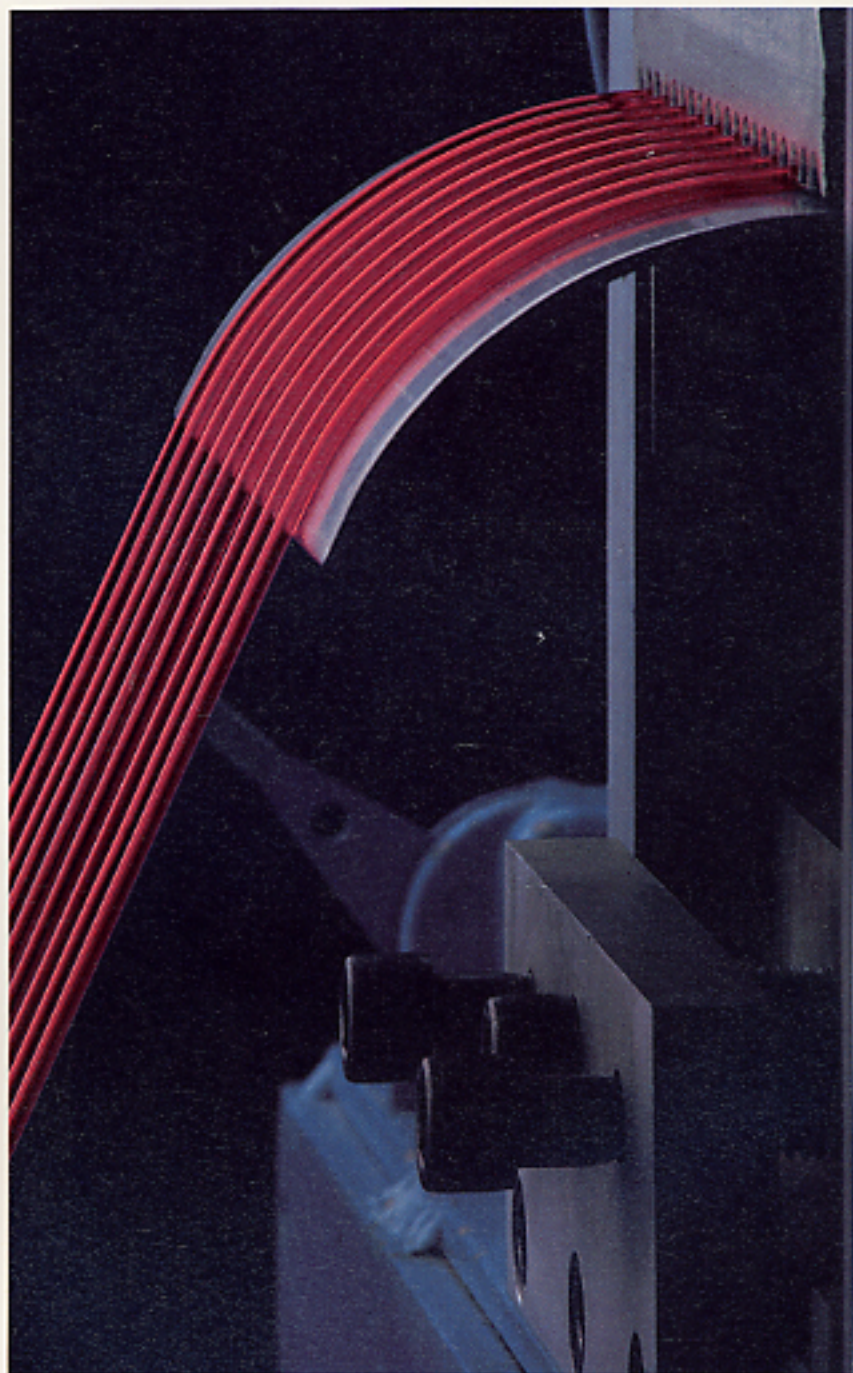
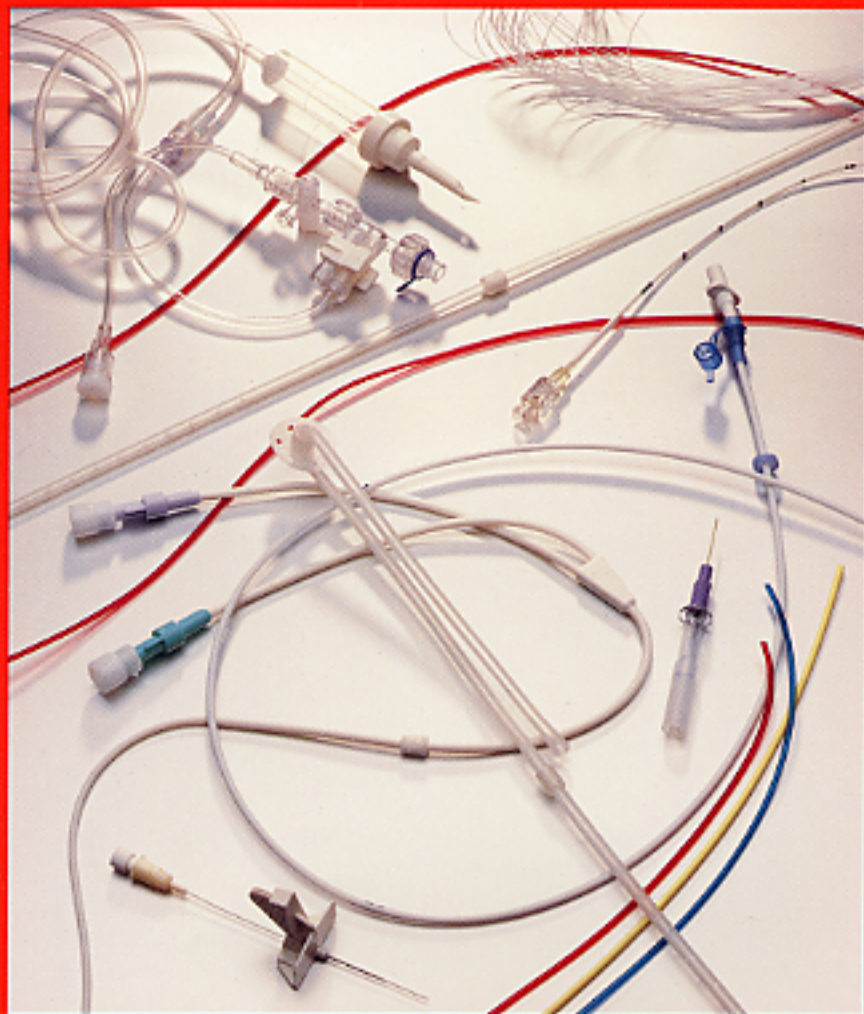


TECOFLEX[®]

Medical
Grade
Aliphatic
Thermoplastic
Polyurethanes

Thermedics





*Front Cover Photo:
Rods of high-purity Tecoflex
resin will be cut into pellets.
These pellets are processed
into tubing and other products.*

*Left: Tecoflex polyurethanes
are excellent materials for a
wide array of medical device
applications.*

Thermedics



John Wood, Thermedics' President, with cartons of Tecoflex pellets ready for shipping.

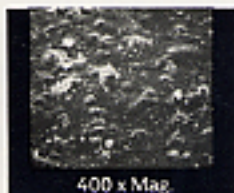
Introduction

Tecoflex® aliphatic polyurethane is a versatile family of elastomeric materials useful in medical device applications requiring biocompatibility, strength and processability. Originally developed through Thermedics Inc.'s research and development of thermoplastics in its artificial heart program, Tecoflex polyurethanes were quickly recognized by medical device manufacturers as excellent materials for implantation into the body, producing minimal tissue reaction or blood clotting. The Tecoflex family of polyurethane is now being used in many medical devices, with new applications continually being found by device manufacturers who encounter demanding tissue or blood contacting situations.

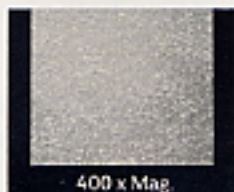
The Challenge

Body tissue and blood present difficult environments for elastomeric components of indwelling medical devices. These components must be able to withstand extended exposure to aqueous environments, body temperature, and the corrosive biochemical composition of blood and body fluids which can degrade many materials. At the same time, the device must cause as few complications to the patient as possible. Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an implanted medical device. Furthermore, the elastomeric component must be strong and easy to manufacture into the small precise shapes and sizes specified by device designers. For example, it is important to keep catheters as small as possible when they are entering the circulatory system—a common application for cardiovascular diagnostic and clinical devices.

Rough radiopaque polyurethane tubing made from dry-compounded pellets.



Smooth radiopaque polyurethane tubing made from Tecoflex pellets.



Tecoflex is a unique family of elastomeric polyurethanes specifically developed to meet the combined challenges of biocompatibility, strength and processability over a wide range of applications. The following pages highlight the special properties of the Tecoflex family of polyurethanes, describe its physical and processing characteristics, and give a brief introduction to the range of Tecoflex products and custom extrusion services.

Tecoflex Resins

Material Description

Tecoflex resins are thermoplastic, aliphatic polyurethanes specially formulated and manufactured for medical applications. They are reaction products synthesized of methylene bis(cyclohexyl) diisocyanate (HMDI), poly(tetramethylene ether glycol) (PTMEG), and 1,4 butane diol chain extender. In its natural state, Tecoflex resin is clear and, because of its aliphatic nature, will not yellow with age. Nor does Tecoflex yellow when exposed to ultraviolet light and oxygen as do aromatic polyurethanes.

Aliphatic resins are processed at lower temperatures than aromatic polyurethanes, for easier extrusion and injection molding. Tecoflex resins are also available in solution castable formula for forming films and coatings or as a two part reactive formula for prototyping complex shapes. All forms of Tecoflex resin are hydrolytically stable because they are formulated using polyether-based macroglycols. This is of key importance in the warm, aqueous environment of blood and tissue, where degradation can cause serious problems for the device—and the patient.

Of greatest importance, Tecoflex's aliphatic composition eliminates the danger of forming methylene dianiline (MDA), which can occur in aromatic polyurethanes if they are improperly processed or overheated. MDA is a known carcinogen and can leach out of aromatic polyurethanes into surrounding tissue or blood. Tecoflex, by its nature, is a safer material, eliminating the worry of MDA formation.

Tecoflex polyurethanes are available in a wide range of durometer (hardness) from 80 Shore A to 72 Shore D, making it a useful material for a large variety of medical device applications. Tecoflex exhibits excellent abrasion resistance and flexural endurance compared to other polymers of similar durometer.

In many soft elastomer medical applications, Tecoflex resin is chosen because of easy processing and high strength. Silicone, another common polymer used in low durometer applications, is difficult to extrude and does not bond easily to components made of other non-silicone materials. Because of the much greater tensile strength of Tecoflex compared to silicone, Tecoflex tubing can have much thinner walls, allowing for either smaller overall diameter or larger inside diameter for increased flow, both of great benefit for indwelling device applications.

For mid-durometer applications where PVC and aromatic urethanes might be considered, the dangers of leachable plasticizers (PVC)

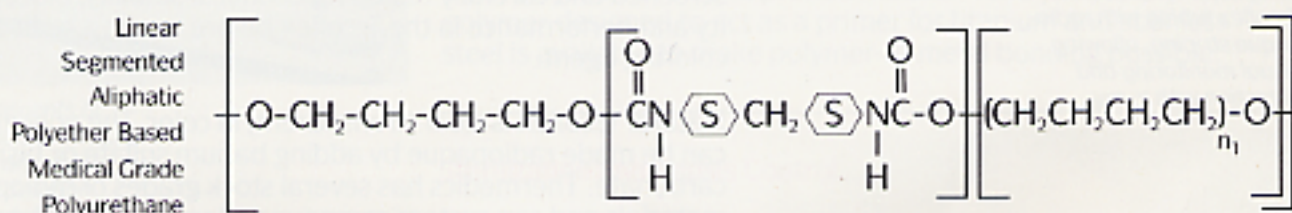


Slabs of freshly polymerized Tecoflex are removed from curing ovens to be produced into uniform sized pellets.

and potential MDA formation (aromatic urethanes) become a concern. Tecoflex also retains its elastomeric characteristics at even low temperatures where PVC becomes brittle. For radiopaque components, Tecoflex polyurethane is radiopacified at the polymerization stage, making it possible to obtain strong, smooth radiopaque device parts with biocompatibility superior to PVC.

Tecoflex urethane compares favorably to harder grade polymers like the fluorinated hydrocarbons. Fluorocarbons are very difficult to bond to other materials, have poor kink resistency and do not produce smooth-surfaced radiopaque tubing. Again, Tecoflex's bondability, strength and processability make it a better choice for harder durometer applications.

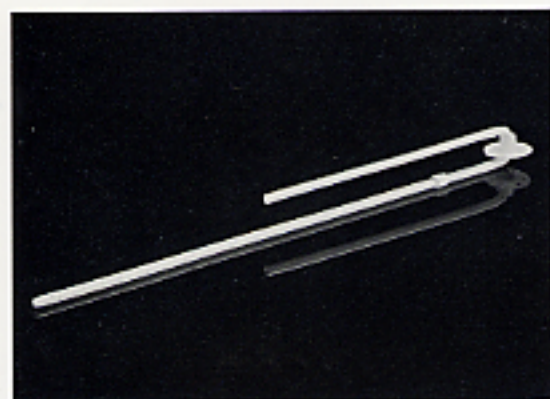
The many requirements necessary for safe, practical use of an elastomer in medical devices quickly narrows the field of suitable materials. Tecoflex aliphatic polyurethanes pass the tests of biocompatibility, processability and chemical stability for medical device use. Wide durometer range and smooth radiopaque surfaces further enhance Tecoflex's standing as an optimal material for medical device components.



Biocompatibility

Based on proven biocompatibility through testing of Tecoflex in contact with tissue and blood, the Tecoflex family of polyurethanes is considered a material of choice for many indwelling medical device applications. The material is in use in a variety of applications including gastric feeding, vascular access, cardiac pacing, and dialysis devices. Tecoflex's blood and tissue compatibility significantly contribute to the quality and effectiveness of devices for use in the body. Here's why.

Tecoflex polyurethane's physical and chemical characteristics have been found to create minimal reactivity to soft tissue, with little foreign body reaction. The Tecoflex surfaces coexist well with tissue,



Thermedics' Peritoneal Dialysis Catheter utilizes Tecoflex tubing with radiopaque striping, allowing visual monitoring and detection with x-ray.

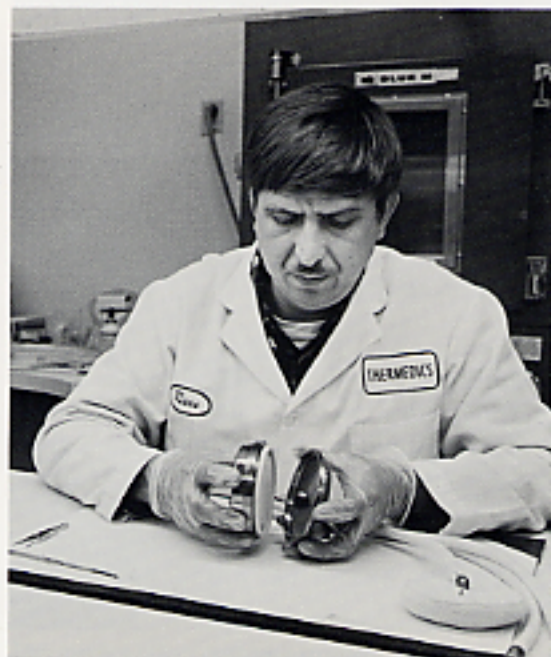
exhibiting little acute or chronic inflammation in short term or long term use compared to other materials. In blood contacting situations, Tecoflex exhibits minimal adhesion of blood components to the polyurethane surface. Of course, there is also no danger of leaching plasticizers or MDA into the bloodstream or tissue fluids. An additional characteristic beneficial for tissue and blood contacting use is a unique softening of Tecoflex tubing as it reaches body temperature and hydrolytic equilibrium. This softening reduces chance of trauma from hard objects pushing against vessel walls. Testing and actual use of Tecoflex in devices is proving Tecoflex to be one of the least thrombogenic and most tissue compatible materials available for indwelling medical device use.

Radiopaque and Color Compounding

Tecoflex polyurethanes can be loaded with radiopaque materials for detection on x-ray or fluoroscope and colored for product identification or coding. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixture and superior smoothness of the final polymer. All additives to the Tecoflex polyurethanes are thoroughly screened and carefully tested for chemical stability, biocompatibility and performance in the Tecoflex before use as a radiopaque or coloring agent.

Natural Tecoflex is clear (transparent) in color. The polyurethane can be made radiopaque by adding barium sulfate or bismuth subcarbonate. Thermedics has several stock grades of radiopaque materials and can custom compound a large variety of durometers to a range of additive from 20% to 40% with barium sulfate. Bismuth subcarbonate is used when extremely high radiopacity is required. Thermedics' custom extrusion services can also produce clear tubing with radiopaque stripes, allowing visual monitoring and detection by x-ray or fluoroscope.

Tecoflex can be dyed for transparent colors using reactive dyes that combine into the urethane chain, creating an unleachable covalent bond for color permanence and non-toxicity. Opaque colors are formed with high density pigment powders that are thoroughly dispersed for color uniformity and smooth consistency. Opaque colors may be chosen from either Munsell or PMS numbers, or custom colors to match existing components may be specified.



Several components of Thermedics' left ventricular assist device are made from Tecoflex solution grade biocompatible polyurethane.

Two-Part and Solution Castable

Two-part reactive materials of HMDI in the A part and PTMEG with 1,4 butane diol in the B part are available in several durometers. These materials have a 12–15 minute pot life when mixed and are tailored for prototyping and casting complicated configurations. The two-part compound comes with detailed instructions on use and mixing information.

The solution grades of Tecoflex have been specially formulated to be dissolved in various solvents for use in solution casting or for coating of medical products. The SG grades differ from the EG grades only in that they contain no melt processing lubricant. See your Thermedics Sales Representative for more details.

Adhesive

Thermedics produces a medical grade urethane-based elastomeric adhesive to bond a variety of polymers. This pressure-sensitive solvent based adhesive is ideal for bonding Tecoflex to other polymers such as polycarbonates, ABS, vinyls, chlorinated SBR rubbers, polyurethanes and primed metals. A two-part epoxy-type polymer designed to act as a primer for titanium and stainless steel is available to make polymer-to-metal bonding possible.

Sterilization and Sepsis Control

Tecoflex products may be sterilized by ethylene oxide or gamma radiation processes. Because heat can degrade polyurethane thermoplastics, the use of steam or dry heat should be carefully tested and reviewed for each specific application before implementation. Physicians choosing to perform a final cleansing before use should apply an antiseptic solution of benzalkonium chloride (1:750 dilution). Alcohol based antiseptics can cause Tecoflex to swell and increase surface tackiness, potentially temporarily decreasing hemocompatibility. Alcohol based bacteriostats should be carefully reviewed and tested before implementation.

Manufacturing Characteristics

Thermedics' polymer research and development is devoted exclusively to medical grade polyurethanes. This intense focus has led to the superb structural strength and workability that Tecoflex exhibits. Tecoflex materials have relatively low melt temperatures and very stable chemical composition and lot-to-lot consistency. The high purity and low melt temperatures make Tecoflex an extremely reliable and predictable material to extrude and mold in all durometers and grades. Tecoflex resins are produced in uniform-sized pellets instead of granulated chunks, for smoother processing and constant extrusion conditions. This helps eliminate surprises and lowers the quantity of material lost as scrap during adjustment and set-up, making Tecoflex polyurethanes a cost-effective alternative for original equipment manufacturers producing medical grade devices or components.

Tecoflex resins are produced in small batches under the strictest manufacturing specifications in accordance with GMP (Good Manufacturing Practice) standards. In addition to high quality standards, small batch compounding allows purchasers of Tecoflex to obtain resins to exact specifications for the research and development of new devices. This eliminates the need to purchase large quantities of a particular material for special use or test purposes, lowering inventory and cost.



Machines producing rods for pelletizing are constantly checked to guarantee the most uniform pellets possible.

Tecoflex Tubing



Custom Tubing Extrusion

Thermedics operates a complete tubing production facility specially designed to extrude Tecoflex polyurethane tubing. All Tecoflex tubing passes strict quality control criteria at each stage of production and conforms to specifications of Good Manufacturing Practices. All Tecoflex tubing extruded at Thermedics is produced on a custom order basis to ensure exact dimensions and configuration.

Tecoflex's excellent working characteristics allow extremely small diameters and very complex lumen configurations to be extruded. Specialty operations such as radiopaque stripe coextrusion are done on a regular basis. Tubing requiring specific radiopaque loadings or exact color matching is also done on a regular basis, allowing manufacturers to order tubing that meets their exact specifications. Thermedics' expert extrusion engineers have developed capabilities to extrude tubing with lumen diameters as small as .005 inch and up to 9 lumens, with orders of tubing with 4 to 6 lumens not uncommon. Thermedics technical staff work with clients to assure all Tecoflex tubing meets exacting dimension, durometer and strength tolerances—ensuring top performance of the tubing in its function within the medical device.

Thermedics offers custom extruded tubing in all durometers and radiopaque grades of Tecoflex polyurethanes.



Cross sections above show a variety of lumen configurations extruded from Tecoflex polyurethanes by Thermedics' tubing service.

Specifications Summary



Cross-sections of Tecoflex tubing are inspected on a profile projector to ensure tight shape and dimensional accuracy.

RESINS AND REACTIVE GRADES

	80A	85A	93A	100A	60D	65D	68D	72D
Natural (Clear)	▲	▲	▲	▲	▲	▲	▲	▲
Barium Sulfate-20%	▲	▲	▲	▲	▲	▲		
Barium Sulfate-40%	▲	▲	▲	▲	▲			
Custom Colors	●	●	●	●	●	●	●	●
Bismuth Subcarbonate	●	●	●	●	●			
Solution Grade	▲	▲	▲		▲			
Two Part Reactive Grade	▲	▲	▲		▲			

● = Custom Order Material

▲ = Available from Stock

Tubing

All Tecoflex tubing is custom extruded in any of the available durometers and grades of Tecoflex resin. Colors and special radiopaque loadings to your specifications.

Adhesive

1-MP — High strength elastomeric adhesive for bonding primed metals, polycarbonates, ABS, plasticized vinyls, chlorinated SBR rubbers, polyurethanes and other polymers.

Primer

2-GP — A two component reactive for priming titanium or stainless steel prior to joining parts with 1-MP. Also may be used as biomedical coating on metals.

Tecoflex® is a registered trademark of Thermochemicals Inc.
Tecoflex polyurethanes are protected by the following U.S. patents:
4,447,590 - 4,523,005 and other U.S. and foreign patents.

For more information about Thermedics' products and services call:

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