Chapter 4
Biomedical elastomers

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4.1 Introduction

Elastomers are described as materials that possess pronounced elasticity and rebound. They can be tough, relatively impermeable to air and water and exhibit resistance to cutting, tearing and abrasion. Often they are modified by compounding to increase their hardness and strength. Or, conversely, they can be soft, compliant and absorbent to water if the need exists. In some instances their properties can closely simulate that of the tissues which they must contact. As biomedical materials they may have originated from commercial formulations or been custom designed from basic chemistry. Those that have been judged as biocompatible have made significant contributions towards the development of successful medical devices. Literally, every basic elastomer has been evaluated at some time for its possible suitability in contact with the body. This would include such materials as natural rubber, styrene rubber, polybutyl rubber, silicone rubber, acrylate rubber, Hypalon®, polyurethanes, fluorinated hydrocarbon rubbers, polyvinyl chloride, thermoplastic vulcanizates and others. Of these, only special medical grade formulations of silicone, polyurethane, polyvinyl chloride and thermoplastic elastomer have continued to be commercially successful.

There are important differences between materials and differences among similar materials within a given generic class. These differences are due to the chemical composition of the polymer, the molecular configuration of the polymer and the presence of functional groups. For instance, polyurethanes of a polyester base were initially tried and found unstable for implantation whereas polyether based polyurethanes were decidedly more stable. Elastomers with aromatic structures behave differently than the polymer having aliphatic structure. Not every material is suitable

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for every application. Some have been found to perform successfully under static conditions but fail or perform undesirably under dynamic situations. Often, the design of a device and the demands upon it will determine if the elastomer chosen is the proper selection. Therefore the material and its use are inseparable. They must be evaluated together. Merely passing an array of physical and biological tests do not confer success. Biocompatibility is an essential element of medical grade elastomers. A set of compatibility tests determine the general physiological acceptability of an elastomer. These consist of passing USP Class VI tests. Additional testing may be required depending upon the device, its area of application and the time it is in contact with tissues. A Master File is often registered by the manufacturer of the basic elastomer with the FDA to attest to its properties, composition and response to biological testing. Demands on medical device manufacturers have never been more stringent. Regulatory pressures, more indepth testing, the threat of litigation plus the constraints of health care cost containment are affecting all aspects of the design and development process and the availability of some biomedical elastomers. A variety of elastomeric materials are available to meet the design challenges presented by medical devices. However, there is still a need for even better materials.

The elastomers that are listed here should be considered in light of their suitability for a specific application. The properties tables should serve as a guide to design options for those in the early stages of the development process. Keep in mind that these properties listed in the tables and the compatibility standings are only indicative of the performance characteristics that an elastomer may exhibit.

4.2 Types of Elastomer

Biomedical elastomers can be classified as to whether they are thermoplastic or thermosetting in nature. Thermoplastic biomedical elastomers are gaining in commercial importance and in some cases replacing traditionally used vulcanized versions. Thermosetting elastomers are irreversibly crosslinked and have had the longest history of medical use. Both groups will be described citing representative medical elastomers that are either commercially available or that may replace elastomers that have been recently withdrawn from the market.

4.2.1 Thermoplastic elastomers

Thermoplastic elastomers (TPEs) are a special class of materials that process similarly to other thermoplastic polymers, yet possess many of the desirable properties of thermoset elastomers. Some TPEs are elastomeric alloys consisting of crosslinked particles of rubber surrounded by a thermoplastic matrix. Others consist of block copolymers and are typified by polyurethanes and styrene polymers.

Depending upon which thermoplastic elastomer is chosen, physical properties can vary over a wide range. They can be either hard, or soft, flexible or stiff, elastic or rigid. For the most part, they are smooth to the touch, yet will form tight seals to surfaces they contact. They can be processed using conventional techniques and equipment and in automated modes. Medical applications consist of such examples as pacemaker lead wire coatings, artificial hearts, and catheters. A wide variety of sundry uses have contributed to patient care and consists of bulbs and bladders, serum caps and tubes, cushions, diaphragms, electrical connectors, flexible medical wire coatings, gaskets, needle shields, pharmaceutical closures, seals, stoppers, tubing, and valves. Most of the TPEs can be sterilized using gas, steam and radiation with very little change in their molecular structures or properties (Table 4.13).

Thermoplastic vulcanizates

Thermoplastic vulcanizates are a separate class of thermoplastic elastomers (TPEs) with Santoprene® as the representative biomedical elastomer.

Santoprene®

This thermoplastic vulcanizate is an olefin based elastomer; an elastomeric alloy. It is totally synthetic and does not contain any natural rubber thereby avoiding many of the allergic reaction problems associated with natural rubber latex. It exhibits outstanding flex-fatigue resistance, low temperature flexibility (-40 °C) and resistance to tearing and abrasion. Its resistance to plastic deformation under tensile and compression stress is another of its features. Santoprene® is reported to be superior to natural rubber in some situations and replaces silicone elastomers in others. It has found use in peristaltic pump tubing, syringe plungers, seals, and caps, tracheal and enteral tubing, vial closures and pump seals, disposable anesthetic hoses, intravenous delivery systems, and other hospital devices. Santoprene® has met USP Class IV requirements for *in vivo* biological reactivity and conforms to the Tripartite Biocompatibility Guidance standards. However, the manufacturer does not recommend Santoprene® for use as part of human implants. The material may be injection molded, extruded, blow molded and thermoformed. For details on physical properties, processing and biocompatibility see Tables 4.1, 4.2, 4.13 and 4.14.

Copolyester ether elastomer

Ecdel™

This copolyester ether TPE is essentially polycyclohexanedimethylcyclohexanedicarboxylate (PCCE). It is reported to possess the chemical resistance, toughness and inertness yet exhibits elastic flexibility over a broad temperature range. Ecdel™ is an unusual elastomer since it has a crystalline structure. Quenching during molding can reduce its crystallinity and impart increased clarity. The material is being used for uniquely designed intravenous bags with built-in bottle necks and fasteners. The material can be injection or blow molded and extruded into film or sheet; but only Ecdel™ 9967 may be processed into tubing. This TPE is also manufactured under the name CR3 by Abbott Labs (Tables 4.2, 4.12, 4.13, and 4.14).

Polyurethane-based elastomers

Polyurethanes are another class of TPEs. They are a large family of chemical compounds that can consist of ether-based, ester-based, polycarbonate-based or polypropylene-based varieties. A number of copolymers are also included;. polyurethanes are combinations of macroglycols and diisocyanates that have been polymerized into tough and elastic materials. TPE polyurethanes have been used for peristaltic pump tubing, parenteral solution tubing and catheters. The tables list the majority of those that are commercially available. Among others are those either of limited supply, available for proprietary use only or that have been successful, but recently discontinued such as:

- Hemothane Sarns Div. of 3M. Restricted to proprietary use.
- Biomer Ethicon, Inc. No longer available through this source.
- Surethane Cardiac Control Systems, Inc. Redissolved Lycra® thread. Some formulations may have a few percent PDMS blended with it. Limited availability.
- Pellethane™ 2360 Dow Chemical, USA. This material is no longer available for medical implant use (see also Pellethane™).
- Angioflex ABIOMED, Danvers, Mass. Restricted to proprietary use.
- Cardiothane Kontrol, Inc. A silicone-urethane interpenetrating polymer network. Limited availability.

Internationally, polyurethanes for medical use have been developed by Italy, China and Japan.

Biospan®

This TPE is a segmented polyurethane and is reported to be not significantly different from biomer in chemistry and molecular weight. It is a polytetra-methyleneoxide-based aromatic polyurethane urea with mixed aliphatic and cycloaliphatic diamine chain extenders. A copolymer of diisopropylamino-ethyl methacrylate and decyl methacrylate are added as a stabilizer. The material is supplied as 25% solids in dimethyl acetamide solvent (Tables 4.3, 4.12, 4.13, and 4.14).

Biospan®-S

This is a silicone modified analog of Biospan® with a different stabilizer. It possesses a silicone-rich surface to enhance thromboresistance while maintaining the bulk properties of Biospan® (Tables 4.3, 4.12, 4.13, and 4.14).

Biospan®-D

This is another version of Biospan® with surface modification by an oligomeric hydrocarbon covalently bonded to the base polymer during synthesis. The additive has a pronounced effect on the polymer surface chemistry but little effect on the bulk properties of the base polymer according to the manufacturer (Tables 4.3, 4.12, 4.13, and 4.14).

Table 4.1 Typical Properties of Thermoplastic Vu1canizates

		Property							
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412		Tear strength pli,die C	Compression set, percent
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%	ASTM D-624	ASTM D-395
Santoprene®	281–45	0.97	45A	435	300	175	100	80	11
Rubber,	281–55	0.97	55A	640	330	250	100	108	23
	281–64	0.97	64A	1,030	400	340	100	140	23
Advanced	281–73	0.98	73A	1230	460	520	100	159	26
Elastomer	281–87	0.96	87A	2,300	520	1,010	100	278	29
Systems	283–40	0.95	40 D	2,750	560	1,250	100	369	32

Table 4.2 Typical Properties of Copolyester Elastomers, PCCE

		Property							
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412		Tear strength pli,die B	Compression set, percent
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%	ASTM D-624	ASTM D-395
Ecdel™	9965							-	
Elastomer,	9966	1.13	95 A	3,500	380	16,000	100	100	40
Eastman	9967							135	
Chemical Co.									

Table 4.3 Typical Properties of Polyurethane-based Elastomers

		Property							
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412		Tear strength pli,die C	Compression set, percent
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%	ASTM D-624	ASTM D-395
Biospan	Biospan®		75A	6000	850	575	100		
segmented	Biospan® D		70 D	6000	1000	550	100		
polyurethane,	Biospan® S		70 D	5500	1050	450	100		
The Polymer									
Technology									
Group, Inc.									
Hydrothane™,	Dry		93 A	7800	580				
Poly Medica	Very dry		95 A	5800	475				
Biomaterials, Inc.	Wet		85 A	5600	500				
	MF-5000	1.15	50 A	3000	500	300	100		
Medicaflex™,	MF-5001	1.15	55 A	3000		300	100		
	MF-5040	1.15	60 A	5000	700	300	100		
Advanced	MF-5041					300	100		
Resin	MF-5056	1.15	65 A	5000	750	500	100		
Technology	MF-5057					550	100		
	MF-5062	1.14	60 A	5000	800	500	100		
	2363-55D	1.15	55 D	6900	390	2500	100	650	25
Pellethane™	2363-55DE	1.15	53 D	6500	450	2300	100	600	30
2363 series,	2363-65D	1.17	62 D	6460		2900	100	1100	30
	2363-75D	1.21	76 D	5810	380		1470		
	2363-80A	1.13	81 A	5200	550	880	100	470	25

(continued)

Table 4.3 (continued)

		Property							
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412		Tear strength pli,die C	Compression set, percent
Dow Chemical	2363-80AE	1.12	85 A	4200	650	890	100	420	30
Co.	2363-80A	1.30	81 A	6860	670	970	100		
	R0120								
	2363-90A	1.14	90 A	5850	500	1700	100	570	25
	2363-90AE	1.14	90 A	6000	550	1475	100	540	
PolyBlend™	PB1000-650		65 D to 75	D6500	350	5300	100	-	-
1000 and	PB1100-55	1.02	55 A	2150	800	135	100	140	55-66
PolyBlend™	PB1100-60	1.02	60 A	2400		210	100	150	50-60
1100,									
Poly Medica	PB1100-75	1.02	75 A	3250	575	420	100	240	45-50
Biomaterials, Inc.	PB1100-80	1.02	80 A	4600	590	555	100	330	25-30
	EG60D	1.09	51 D	7829	363	2000	100		
Tecoflex®,	EG60D-B20	1.32	55 D	7484	370				
	EG65D	1.10	60 D	8074	335	2500	100		
	EG65D-B20	-	63 D	6986	321				
Thermedics,	EG68D	1.10		8686	332				
Inc.	EG72D	1.11	67 D	7739	307	3400	100		
	EG80A	1.04	72 A	5640	709	400	100		
Thermedics,	EG80A-B20	1.24	73 A	5571	715				
Inc.	EG85A	1.05	77 A	6935	565	700	100		
	EG85A-B20	1.25	83 A	5282	632				
	EG85A-B40	1.51	84 A	5093	559				
	EG93A	1.08	87 A	7127	423	1100	100		

	EG100A	1.09	94 A	8282	370	1800	100		
	EG100A-B20	1.29	93 A	7104	369				
	EG100A-B40	1.54	96 A	5607	360				
	1055D	1.16	54 D	9600	350	2500	100		
Tecothane®	1065D	1.18	64 D	10 000	300	3200	100		
	1074A	1.10	75 A	6000	530	530	100		
	1075D	1.19	75 D	8300	240	3600	100		
Thermedics,	1085A	1.12	85 A	7000	450	800	100		
Inc.	1095A	1.15	94 A	9400	400	1600	100		
	2055D	1.36	55 D	9000	360	2700	100		
	2065D	1.38	67 D	8500	300	3100	100		
	2074A	1.30	77 A	5500	580	510	100		
	2075D	1.40	77 D	7600	230	3000	100		
	2085A	1.32	87 A	6600	550	800	100		
	2095A	1.35	97 A	8200	450	1600	100		
	5187	1.20	87 A	6000	500	750	100	500	12
Texin™	5265	1.17	65 D	6000	460	3300	100	1200	20
	5286	1.12	86 A	6000	550	700	100	500	16
Miles, Inc.	5370	1.21	70 D	6000	180	4500	100	900	
	DP7-3002		88 A	2208	579	815	100	399	—
	DP7-3003	—	50 D	3714	458	1049	100	564	
	DP7-3004		55 D	4783	392	1766	100	819	

Table 4.4 Typical Properties of Polycarbonate-based Polyurethane

		Property						
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412		Tear strength pli, die C
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%	ASTM D-624
	PC-3555D	1.15	60 D	7000	350	1500	100	
Carbothane™	PC-3555D-B20	1.36	57 D	8300	380	1600	100	
	PC-3572D	1.15	71 D	8500	300	4100	100	
Thermedics,	PC-3572D-B20	1.35	71 D	8400	310	3400	100	
Inc.	PC-3575A	1.15	73 A	4400	500	380	100	
	PC-3575A-B20		73 A	3500	600	410	100	
	PC-3585A	1.15	84 A	6500	390	640	100	
	PC-3585A-B40	1.68	89 A	3800	521	700	100	
	PC-3595A	1.15	95 A	6500	520	900	100	
	PC-3595A-B20	1.36	96 A	8300	390	1100	100	
Chronoflex™	Chronoflex™		70 A	7500	500	700	100	
AR, Poly Medica Bio-materials, Inc.	AR							
Corethane®	TPE 55D	1.211	55 D	7000-	365-	1850-	100	
				8500	440	2200		
and	TPE 75D	1.216	75 D	7000-	255-	5300-	100	
				9100	320	5700		
	TPE 80A	1.179	80 A		400-	770-		
					490	1250		
Corhesive™,	Corhesive™	1.179	80 A	6500-	400-	770-	100	
Corvita Corp.	(cured)			7500	900	1250		
Texin™ 5370, 5370 Miles, Inc.		1.21	70 D	6000	180	4500	100	900

Table 4.5 Typical Properties of Polypropylene-based Elastomers

Property							
		Specific gravity	Durometer hardness shore	Tensile strength, psi	Elongation, percent	Tear strength pli,die B	Compression set, percent
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	ASTM D-624	ASTMD-395
Sarlink®	3260	0.95	60 A	870	619	183	42
medical grade							
DSM Thermoplastic							
Elastomers, Inc.							

Hydrothane™
Hydrothane™ is a TPE hydrogel belonging to the polyurethane family of polymers. Hydrothane™ is an aliphatic material with water absorption capabilities ranging from 5 to 25% by weight while still maintaining high tensile strength and elongation. Because of its water absorption capacity, Hydrothane™ is reported to be bacteria-resistant and lubricious. The polymer can be processed by conventional extrusion and injection molding techniques. It can also be dissolved in dimethyl acetamide solvent to produce a 25% solids solution suitable for dip-coating and other solution processing techniques (Tables 4.3, 4.12, and 4.13).

Medicaflex™
The Lambda series of Medicaftex is a polyurethane-based TPE polymer that exhibits low modulus characteristics with high tear strength and abrasion resistance. Those listed in the tables have passed USP Class VI compatibility tests and have been used as replacements in some natural rubber latex and silicone rubber applications. The polymer has been applied to uses such as catheters, tubing and films where softness, low durometer hardness, low modulus or high elongation are needed (Tables 4.3, 4.12, and 4.13).

Pellethane™ polyurethane elastomers
The 2363 series Pellethane™ TPE elastomers have a wide range of durometer hardness and are noted for their high tensile and tear strength and abrasion resistance. Chemically they are classed as polytetramethylene glycol ether polyurethanes. The ether series is the most widely used for medical applications although polyester versions of Pellethane™ are useful for some applications. None of these polymers have the disadvantage of containing plasticizers which can migrate out of the polymer over time resulting in reduction in physical properties. Medical tubing made from Pellethane™ polymer is widely used. These TPEs are unaffected by ethylene oxide gas, gamma radiation and electron beam sterilization procedures. Pellethane™ can be processed by injection molding and extrusion. For details on physical properties, processing and biocompatibility (Tables 4.3, 4.12, and 4.13).

Table 4.6 Typical Properties of Plasticized Polyvinyl Chloride

	Property						
		Specific gravity	Durometer shore	Tensile strength, psi	Elongation, percent	Modulus ASTM D-412	
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%
	3511TX-02	1.12	35 A	1110	525	235	100
Elastichem™	4011TX-02	1.16	40 A	1300	500	266	100
PVC,	5011TX-02	1.16	50 A	1650	465	426	100
Colorite	5511TX-02	1.18	55 A	1790	465	455	100
Plastics Co.	6011TX-02	1.18	60 A	1936	465	488	100
	7011TX-02	1.21	70 A	2667	400	952	100
	7511TX-02	1.22	75 A	3000	360	1400	100
	8011TX-02	1.23	80 A	3646	330	2025	100
	0-1234	1.21	58 A	1400	400	600	100
Ellay™ PVC,	0-1290	1.26	83 A	2750	275	1500	100
	0-1541	1.23	81 A	2400	300	1400	100
	0-1554	1.21	70 A	2000	400	950	100
Ellay, Inc.	0-2112	1.24	82 A	2650	320	1200	100
	0-2129	1.24	83 A	2670	310	1500	100
	0-2202	1.54	75 A	2360	270	1190	100
	0-2609	1.20	68 A	1950	410	800	100
	0-2610	1.24	83 A	2460	295	1450	100
	0-2623	1.24	82 A	2550	325	1350	100
	0-2631	1.19	65 A	1800	390	650	100
	0-3110	1.22	74 A	2100	355	1000	100
	0-3115R	1.20	68 A	1900	400	800	100
	0-3119	1.22	75 A	2150	350	1100	100
	0-3138R	1.22	75 A	2200	350	1075	100
	0-3140R	1.25	87 A	2850	330	1600	100
	0-3147	1.28	95 A	3100	250	2350	100
	0-3149R	1.23	78 A	2400	340	1150	100
	0-3154	1.19	65 A	1750	410	725	100
	0-3155R	1.20	68 A	1850	390	780	100
	0-3166R	1.25	85 A	2700	320	1650	100
	0-3195	1.27	90 A	2950	280	2210	100
	0-3200	1.18	60 A	1600	450	525	100
Ellay™ PVC,	0-3201	1.21	70 A	2000	340	800	100
	0-3224R	1.21	77 A	2300	345	1100	100
	0-3231R	1.26	88 A	3000	280	1800	100
Ellay, Inc.	0-4106R	1.25	85 A	2650	300	1600	100
	0-4108	1.25	85 A	2750	300	1600	100
	0-4109R	1.25	85 A	2800	310	1700	100
	0-4113	1.31	100 A	3960	184	3200	100

(continued)

Table 4.6 (continued)

Property							
						Modulus	
				Tensile		ASTM	
		Specific gravity	Durometer shore	strength, psi	Elongation, percent	D-412	
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%
	0-4114	1.20	67 A	1900	400	780	100
	0-4115	1.26	87 A	2800	295	1650	100
	0-4116R	1.27	90 A	2950	265	2100	100
Ellay, Inc.	0-4120	1.21	68 A	2180	400	830	100
	0-4121	1.23	81 A	2550	325	1400	100
	0-4122	1.33	110 A	4500	135	4180	100
	0-4124R	1.28	95 A	3050	250	2200	100
	0-4125	1.24	80 A	3150	355	1310	100
	0-4129	1.18	63 A	1670	430	620	100
	0-4132	1.21	70 A	2000	395	900	100
	0-4135	1.23	80 A	2550	320	1260	100
	0-4140	1.23	80 A	2500	330	1250	100
	0-4150	1.26	88 A	2900	290	2200	100
	0-5210C	1.26	82 A	2300	225	1250	100
	BB-69	1.23	78 A	2200	340	1150	100
	EH-222C	1.21	70 A	2050	365	1100	100
	ES-2967ZPH	1.22	75 A	2300	360	1200	100
Geon® PVC,	121AR	1.4		2800	380		
	213	1.4		2205	379	1010	100
B. F. Goodrich							
Co.	250x100			1700-1850	430-460	400-500	100
Multichem™	6014	1.15	60 A	1640	540	400	100
PVC,	7014	1.19	70 A	2040	600	625	100
Colorite	8014	1.22	80 A	2100	500	1000	100
Plastics Co.	8514	1.24	85 A	2250	530	880	100
	3300-45 NT	1.13	45 A	1100	480	325	100
Teknor™	3300-50 NT	1.14	50 A	1220	460	370	100
PVC,	3300-55 NT	1.16	55 A	1500		520	100
	3300-60 NT	1.17	60 A	1550	450	560	100
Teknor Apex	3300-68 NT	1.18	68 A	1850	430	690	100
Co.	3300-75 NT	1.20	75 A	2150	420	900	100
	3300-80 NT	1.21	80 A	2400		1,320	100
	3300-85 NT	1.23	85 A	2800	380	1,560	100
	3300-90 NT	1.25	90 A	3100	340	2,100	100
	3310-50 NT	1.35	50 A	1000	430	330	100
	3310-55 NT	1.35	55 A	1100	410	400	100
	3310-60 NT	1.35	60 A	1300	400	480	100

(continued)

Table 4.6 (continued)

Property							
Product and Manufacturer	Product no.	Specific gravity ASTM D-792	Durometer shore ASTM D-2240	Tensile strength, psi ASTM D-412	Elongation, percent ASTM D-412	Modulus ASTM D-412 psi	%
	3310-65 NT	1.35	65 A	1500	390	590	100
	3310-70 NT	1.35	70 A	1770	380	700	100
	3310-75 NT	1.35	75 A	1900	370	800	100
	3310-80 NT	1.35	80 A	2200	360	1,050	100
	3310-85 NT	1.35	85 A	2500	340	1,470	100
	3310-90 NT	1.35	90 A	2900	330	1,900	100
Teknor Apex	90A471R-60NT	1.16	60 A	1500	450		
Co.	90A471R-65NT	1.17	65 A	1750	440		
	90A471R-70NT	1.18	70 A	1900	430		
	90A471R-75NT	1.20	75 A	2150	420		
	90A471R-80NT	1.23	80 A	2690	380		
	90A471R-85NT	1.23	85 A	2800			
	90A471R-90NT	1.27	90 A	3350	360		

Notice Regarding Long-Term Medical Implant Applications

The Dow Chemical Company does not recommend Pellethane™ elastomers for long-term medical implant applications in humans (more than 30 days). Nor do they recommend the use of Pellethane™ elastomers for cardiac prosthetic devices regardless of the time period that the device will be wholly or partially implanted in the body. Such applications include, but are not limited to, pacemaker leads and devices, cardiac prosthetic devices such as artificial hearts, heart valves, intra-aortic balloon and control systems, and ventricular bypass assist devices. The company does not recommend any non-medical resin (or film) product for use in any human implant applications.

PolyBlend™ polyurethane

This TPE has been described as an aromatic elastoplastic polyurethane alloy. It possesses a low coefficient of friction, low extractables, and dimensional stability. Hardness ranges from 65 to 75 Shore D. The material is classified for short-term (29 days or less) implantation. Clear and radiopaque formulations are available. Tubing should be annealed at 80°C for four hours to reduce crystallinity (Tables 4.3, 4.4, 4.12, and 4.14).

Tecoflex® polyurethane

Tecoflex is an aliphatic polyether-based polyurethane that is available in clear and radiopaque grades. They are reaction products of methylene bis (cyclohexyl) diisocyanate (HMDI), poly (tetramethylene ether glycol) (PTMEG), and 1,4 butane diol chain extender. The manufacturer claims that the aliphatic composition of Tecoflex®

eliminates the danger of forming methylene dianiline (MDA) which is potentially carcinogenic. MDA can be generated from aromatic polyurethanes if they are improperly processed or overheated. Tecoflex has been reported to crack under stress when implanted, long-term, in animals. An advantage of Tecoflex is that it softens considerably within minutes of insertion in the body. This feature can offer patient comfort for short-term applications such as catheters and enteral tubes; it is also reported to reduce the risk of vascular trauma (Tables 4.3, 4.12, and 4.13).

Tecothane®

Tecothane® is an aromatic polyether-based TPE polyurethane polymer. It has processibility and biocompatibility characteristics similar to Tecoflex® except that it is an aromatic rather than an aliphatic polyurethane. Tecothane® is synthesized from methylene diisocyanate (MDI), polytetramethylene ether glycol and 1,4 butanediol chain extender. By varying the ratios of the reactants, polymers have been prepared ranging from soft elastomers to rigid plastics. The manufacturer of Tecoflex® and Tecothane® point out that there is not much difference between medical-grade, aliphatic and aromatic polyether-based polyurethanes with regard to chemical, mechanical and biological properties. However, they caution that with improper processing of Tecothane® (e.g., high moisture content or steam sterilization) it is possible to form measurable amounts of methylene dianiline (MDA), a listed carcinogen. The use of ethylene oxide or gamma radiation are suitable sterilizing agents that do not affect the chemical or physical properties (Tables 4.3, 4.12, and 4.13).

Texin™

There are four basic polymer formulations of Texin polyurethane TPE that may be suitable for medical applications. They range in hardness and flexural modulus. Texin elastomers are produced by the reaction of diisocyanate with a high molecular weight polyester or polyether polymer and a low molecular weight diol. The polyethers (products 5286 and 5265) offer greater hydrolytic stability and stress crack resistance. The polyesterbased polyurethane (product 5187) and the polyester polyurethane/ polycarbonate blend (product 5370) possess high impact strength and high stiffness along with useful low-temperature properties. Texin is not recommended for implants of greater than 30 days duration. Texin should not be sterilized by autoclave or use of boiling water. Other advantages offered by Texin TPUs are that plasticizers are not necessary to achieve flexibility, the amount of extractables are low, and they possess high tensile strength, high tear strength, and high abrasion resistance. Texin polyurethanes are hydroscopic and will absorb ambient moisture. They can be processed by extrusion and injection molding if thoroughly dried beforehand. As with all chemical systems, the proper use and handling of these materials can not be over-emphasized (Tables 4.3, 4.12, and 4.13).

Texin™ 5370 is a blend of polyester-based polyurethane and polycarbonate. It offers high impact strength and high stiffness. Steam sterilization or boiling should be avoided (Tables 4.3, 4.12, and 4.13).

Table 4.7 Typical Properties of Styrene-based Thermoplastic Elastomers

		Property								
		Specific gravity	Durometer hardness shore		Tensile strength, psi	Elongation percent	Modulus ASTM D-412		Tear strength pli,die B	Compression set, percent
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240		ASTM D-412	ASTM D-412	psi	%	ASTM D-624	ASTM D-395
	R70-001	0.90	50	A	1200	900	150	100		16
C-Flex®,	R70-003	0.90	70	A	1280	760	340	100		25
	R70-005	0.90	30	A	1400	950	100	100		11
	R70-026	0.90	90	A	1830	650	1,010	100		
Consolidated	R70-028	0.90	35	A	990	800	120	100		13
Polymer	R70-046	0.90	34	A	1320	940	110	100	135	12
Technologies, Inc.	R70-050	0.90	48	A	1250	880	170	100	100	18
	R70-051	0.90	74	A	1140	680	370	100	150	28
	R70-058	0.94	70	A	2080	660	300	100	120	55
	R70-057	0.92	40	A	1220	890	100	100	90	33
	R70-068	0.93	50	A	1630	850	140	100	110	38
	R70-072	0.90	60	A	1270	780	240	100		20
	R70-081	0.90	45	A	1440	920	120	100		17
	R70-082	0.90	61	A	1270	860	230	100	130	19
	R70-085	0.90	50	A	1380	750	200	100		17
	R70-089	0.90	45	A	1640	700				
	R70-091	0.90	50	A	1280	780	130	100		
	R70-116	0.90	30	A	1105	810	100	100	84	24
	R70-190	0.90	5	A	270	1010	20	100		
	R70-214	0.90	18	A	450	780				
	D-2103	0.94	70	A	4300	880	400	300	205	

Kraton®,	D-2104	0.93	27	A	1700	1350	200	300	180	
	D-2109	0.94	44	A	950	800	300	300	160	
Shell	G-2701	0.90	67	A	1600	800	480	300	260	
Chemical	G-2703	0.90	63	A	1200	670	470	300	230	
Co.	G-2705	0.90	55	A	850	700	400	300	140	38
	G-2706	0.90	28	A	850	950	130	300	140	
	G-2712	0.88	42	A	840	820	250	300	140	

Polycarbonate-based polyurethanes

Carbothane™
This medical grade TPE polyurethane is the reaction product of an aliphatic diisocyanate, a polycarbonate-based macrodiol, and a chain terminating low molecular weight diol (Tables 4.4, 4.12, and 4.13).

ChronoFlex™ *AR.*
Available as a dimethyl acetamide solution, this segmented, aromatic, polycarbonate-based TPE polyurethane was designed to mimic Ethicon Corporation's Biomer. The polymer is made from the addition of diphenylmethane 4,4'-diisocyanate to a polycarbonate diol followed by addition of a mixture of chain extenders and a molecular weight regulator. The polymer is believed to be resistant to environmental stress cracking such as that experienced by other polyurethanes coated onto pacemaker leads (Tables 4.4, 4.12, and 4.13).

Coremer™
Specifically designed as an 80 Shore A durometer TPE, this is a diamine chain extended version of Corethane®. Coremer™ solution cast films have a low initial modulus and high flex fatigue life. Information as to long-term biostability is not available at this time (Tables 4.4 and 4.13).

Corethane®
A polycarbonate TPE polyurethane that claims biostability is achieved through its replacement of virtually all ether or ester linkages with carbonate groups. The soft segment is composed of a polycarbonate diol formed by the condensation reaction of 1,6-hexanediol with ethylene carbonate. The polycarbonate diol is converted to a high molecular weight polyurethane by the reaction with 1,4-methylene bisphenyl diisocyanate (MDI) and 1,4-butanediol. It is reported to be resistant to environmental stress cracking as experienced with insulation on pacemaker lead wires. The polymer can be extruded, injection molded or compression-molded, and can be bonded with conventional urethane adhesives and solvents (Tables 4.4, 4.12, 4.13, and 4.14).

Corhesive™
Corhesive™ is a solvent-free, two-component reaction adhesive system for use with polyurethanes, plasma treated silicones and certain metals (Tables 4.4, 4.12, 4.13, and 4.14).

Polypropylene-based elastomers Sarlink®
This is a polypropylene-based TPE that has been used as a replacement for medical stoppers previously made from butyl rubber. Sarlink® has the characteristics typical of rubber vulcanizates such as elasticity, flexibility, high coefficients of friction and softness. Sarlink® combines gas impermeability without concern for contamination of biological medium. Applications for medical grade Sarlink® are inserts on syringe plungers, reusable injection caps, vacuum assisted blood sampling tubes, plus

flexible grade tubing. The number of stoppers produced from Sarlink annually number in the billions. The material can be injection molded, blow molded, extruded, calendered, and thermoformed on standard processing equipment. It can be thermal bonded or adhesive bonded (Tables 4.5, 4.12, and 4.13).

Polyvinyl chloride elastomers

Polyvinyl chloride polymer is polymerized from vinyl chloride monomers. It is a hard material which can be made soft and flexible through the addition of a plasticizer or a copolymer. As such, it resembles an elastomer and can be included with other TPEs. Also optionally added to PVC are fillers, stabilizers, antioxidants and others. A typical PVC plasticizer for medical products is di(2-ethylhexyl) phthalate (also known as dioctyl phthalate, DOP). Some producers of PVC also offer non-phthalate formulations. PVC has been used extensively for blood bags, blood tubing, endotracheal tubes, catheters and fittings, urology tubes, intravenous tubing, respiratory devices and dialysis sets. Leaching of the plasticizer can offer difficulties if the application is not short-term. Medical grade PVC is available from B.F. Goodrich under the name Geon® RX, Elastichem™ PVC, Ellay™ PVC, Multichem™ PVC, Teknor™ PVC, AlphaGary and others. PVC polymers have also been incorporated as additives to polyurethane to alter the properties of the latter.

Elastichem™ PVC.

This polyvinyl chloride compound family is highly elastomeric and exhibits a dry non-tacky surface even at hardnesses as low as 40 Shore A durometer. Their rubber-like resilience, high elongation and low permanent set and fatigue resistance offer advantages over conventional formulations (Tables 4.6, 4.12, and 4.13).

Ellay™ PVC.

Compounds from Ellay Corp. are available with Shore hardness ranges from 55 A to 100 A. The polymers have been applied to medication delivery systems, blood collection, processing and storage, gastro-urological devices and collection systems. Product numbers ending in 'R' are special radiation resistant grades (Tables 4.6, 4.12 and 4.13).

Geon® PVC.

Geon® PVC is associated with vinyl examination gloves. For this use, Geon® recommends a combination of Geon® 121 AR and 213. For a more 'latex type' feeling, Goodtouch 250x100 is recommended. Typical film samples have passed patch insult tests when worn against the skin for extended periods (Tables 4.6, 4.12 and 4.13).

Multichem™ PVC

This line of PVC polymers consist of alloys of PVC in combination with other polymers. They display notable dynamic properties and resistance to migration and extraction. These non-toxic PVC compounds (includes Multichem™ and Elastichem™) have over 25 years of experience in the medical field (Tables 4.6, 4.12 and 4.13).

Teknor™ Apex PVC
This extrudable PVC has found use as tubing for blood transport and delivery systems, dialysis and enteral feeding systems, oxygen delivery systems, catheters, and drainage systems. Product numbers containing an R are special radiation resistant grades (Tables 4.6, 4.12 and 4.13).

Styrene-based elastomers

C-Flex®TPE.
C-Flex® thermoplastic elastomers are based on styrene/ethylene-butylene/styrene block copolymers. C-Flex® polymers designated as 'medical grade' are clear and can be processed using conventional extrusion and injection molding equipment. They have been tested using Good Laboratory Practices and have successfully passed USP Class VI, biocompatibility tests. Translucent versions have high rebound values at ultimate elongation. Medical tubing, ureteral stents, blood pumps, feeding tubes and nephrostomy catheters are successful uses of this material (Tables 4.7, 4.12 and 4.13).

Kraton®
Kraton® elastomer consists of block segments of styrene and rubber monomers and are available as Kraton® D and G series. The D series is based on unsaturated midblock styrene-butadiene-styrene copolymers whereas the G series is based on styrene-ethylene/butylene-styrene copolymers with a stable saturated midblock. Listed among the attributes of both series are such features as low extractables, dimensional stability, vapor and gas transmission properties, ease of sterilization, softness and clarity. They exhibit elastomeric flexibility coupled with thermoplastic processibility (Tables 4.7, 4.12, 4.13).

4.2.2 crosslinked elastomers

Natural rubber
Natural rubber (cis-polyisoprene) is strong and one of the most flexible of the elastomers. The material has been used for surgeon's gloves, catheters, urinary drains and vial stoppers. However, because it has the potential to cause allergic reactions thought to be due to the elution of entrapped natural protein, this elastomer is being used less now than in the past. Safer substitutes are being selected.

Silicone elastomers
Silicone elastomers have a long history of use in the medical field. They have been applied to cannulas, catheters, drainage tubes, balloon catheters, finger and toe joints, pacemaker lead wire insulation, components of artificial heart valves, breast implants, intraocular lenses, contraceptive devices, burn dressings and a variety of

associated medical devices. A silicone reference material has been made available by the National Institutes of Health to equate the blood compatibility of different surfaces for vascular applications. This material is available as a silica-free sheet. Contact the Artificial Heart Program, NHBLI, NIH, Bethesda, Md. for further information.

The silicone elastomers most commonly used for medical applications are the high consistency (HC) and liquid injection molding (LIM) types. The former is most often peroxide cured and the latter platinum cured although there are variations. Both materials are similar in properties. LIM offers greater advantages to the medical device molder and is gaining in popularity. This form of silicone may become the molder's material of choice within the next few years.

High consistency (HC) silicone elastomer

High consistency silicone elastomer consists of methyl and vinyl substituted silicones with aromatic and fluorinated functional groups in some formulations. For the most part, they are peroxide crosslinked. Items are usually compression or transfer molded (Tables 4.8).

Liquid injection molding (LIM) silicone elastomer

Liquid injection molding (LIM) with liquid silicone rubber (LSR) is fast becoming the technique of choice for processing silicone elastomers. Modifications of conventional injection molding equipment are required. For example, pumps to handle two components being injected simultaneously are required. The heaters on the injection barrel and nozzle are replaced by water cooled jackets. The mold is heated in the range of 300 to 400°F. Because the (LSR) flows easily, injection pressures are low (800 to 3000 psi). Elastomeric items cure rapidly in the mold (e.g., a 7 gram part will crosslink in about 15 seconds at 350 °F). Many formulations rely on platinum as a crosslinker. Perhaps in the future, the majority of silicone rubber molded parts will be made in this fashion. Appropriate equipment is commercially available.

Tables 4.8, 4.9, 4.10 and 4.11 list the silicones made by Applied Silicone Corp., Dow Corning Corp., and NuSil Technologies. Table 4.12 lists their biocompatibility status and Table 4.13 recommended sterilization methods. Dow Corning no longer offers the following materials for general sale:

- Silastic MDX 4–4515
- Silastic MDX 4–4515
- Silastic Q7–2245
- Dow Corning Q7–2213

Further, they have discontinued the sale of all implant grade materials.

Other silicones

Silicones and polyurethanes have been used to produce denture liner materials and maxillofacial prostheses. Most of these materials are silicone based, e.g., Flexibase,

Table 4.8 Typical Properties of High Consistency (HC) Silicone Elastomers

		Property				
Product and Manufacturer	Product no.	Specific gravity ASTM D-792	Durometer hardness, shore ASTM D-2240	Tensile strength, psi ASTM D-412	Elongation, percent ASTM D-412	Tear strength pli, die B ASTM D-624
	40039	1.12	35 A	1600	1200	200
Applied Silicone	40040	1.15	50 A	1500	900	220
Medical Implant	40041	1.20	66 A	1200	900	260
Grade,	40042	1.20	78 A	1200	600	280
Applied Silicone	40043	1.12	23 A	1100	1500	160
Corp.	40044	1.12	33 A	1600	1015	150
	40045	1.15	51 A	1400	600	190
	40046	1.20	66 A	1200	500	250
	40063	1.20	70 A	1400	850	280
	MED-2174	1.15	52 A	1200	715	200
NuSil Silicone,	MED-2245	1.13	41 A	1300	700	140
	MED-4515	1.15	52 A	1350	450	90
NuSil Technology	MED 4516	1.21	72 A	1175	370	80
	MED-4735	1.10	35 A	1310	1250	200
	MED 4750	1.15	50 A	1350	810	230
	MED 4755	1.14	57 A	1375	800	300
	MED 4765	1.20	65 A	1100	900	240
	MED-4770	1.17	70 A	1375	700	300
	MDX4-4210	1.10	25 A	550	350	50
Silastic ®	Q7-4535	1.10	33 A	1200	1015	160
Medical Materials,	Q7-4550	1.14	51 A	1375	600	170
	Q7-4565	1.20	66 A	1000	550	210
Dow Corning	Q7-4720	1.10	23 A	1200	1100	150
Corp.	Q7-4735	1.10	35 A	1050	1200	200
	Q7-4750	1.14	50 A	1300	900	230
	Q7-4765	1.14	50 A	1300	900	230
	Q7-4780	1.22	78 A	850	600	190

Table 4.9 Typical Properties of Liquid Injection Molding (LIM) Silicone Elastomers

		Property				
Product and Manufacturer	Product no.	Specific gravity ASTM D-792	Durometer hardness, shore ASTM D-2240	Tensile strength, psi ASTM D-412	Elongation, percent ASTM D-412	Tear strength pli, die B ASTM D-624
	40023	1.11	10 A	500	750	80
Applied Silicone	40024	1.11	20 A	800	600	140
Medical Implant	40025	1.12	30 A	950	600	150
Grade,	40026	1.12	40 A	980	450	170
Applied Silicone	40027	1.13	50 A	1000	400	190
Corp.	40028	1.13	60 A	1100	350	220
	40029	1.10	30 A	900	300	80
	40071	1.14	70 A	1200	350	220
	40072	1.10	25 A	650	400	60
	40082	1.10	40 A	900	250	110
NuSil Silicone,	MED-6210	1.04	50 A	1000	100	35
	MED-6233	1.03	50 A	1200	300	75
NuSil Technology	MED-6382	1.13	45 A	400	200	
	MED-6820	1.05	40 A	750	125	25
Silastic®	Q7-4840	1.12	40 A	950	425	150
Medical Materials,	Q7-4850	1.14	50 A	1350	550	225
Dow Corning Corp.	Q7-6860	1.16	60 A	1300	450	250

Molloplast-B, Prolastic, RS 330 T-RTV, Coe-Soft, Coe-Super Soft, Vertex Soft, PERform Soft, and Petal Soft. Other custom made elastomers have been applied to maxillofacial prostheses, e.g., Cosmesil, Silastic® 4-4210, Silastic® 4-4515, Silicone A-102, Silicone A-2186, Silskin II, Isophorone polyurethane, and Epithane-3. Denture liners with acrylic and silicone include Coe-Soft, Coe Super-Soft, Vertex Soft, Molloplast-B and Flexibase.

Dispersions
Solvent solutions of polyurethane elastomers and silicone elastomers are given in Table 4.10. These materials are helpful in casting thin films and odd or complex shapes.

Table 4.10 Typical Properties of Elastomeric Dispersions

		Property						
		Specific gravity	Durometer hardness	Tensile strength, psi	Elongation percent	Modulus ASTM D-412		Tear strength pli,die B
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	psi	%	ASTM D-624
	40000	1.10	35 A	1800	800		185	
Applied Silicone	40001	1.18	32 A	1200			200	
Medical Implant	40002	1.08	24 A	800	700		60	
Grade,	40016	1.10	35 A	1800	800		185	
Applied Silicone	40021	1.08	24 A	1000			100	
Corp.	40032	1.19	40 A		500		120	
	MED-2213	1.13	Shore 00,82	1300	700	190	200	140
NuSil Silicone,	MED-6400	1.08	32 A	1250		325	300	150
	MED2-6400	1.08	32 A	1250	800			
NuSil Technology	MED-6600	1.10	20 A	1000		275	300	90
	MED2-6600	1.10	25 A	1000	750	325	300	
	MED-6605	1.08	25 A	900	1000	75	175	100
	MED3-6605	1.08	25 A	900	1000	100	200	125
	MED-6607	1.10	40 A	900	650	-		130
	MED-6640	1.12	30 A	1650	1100	150	100	280
	MED2-6640	1.12	30 A	1750		100	100	275
	MED2-6650	1.15	35 A	1100	750	200	300	
Silastic ® Medical Materials, Dow Corning Corp.	Q7-2630	-	Shore 00, 70	800	900	50	200	-

Product no.	Form	viscosity cp.	Solvent System Used	Cure System	Chemical Type
40000	35% solids, 1 part	2000	Xylene	Platinum addition	Methyl vinyl siloxane
40001				Phenyl vinyl	
40002	32% solids, 1 part	500		Acetoxy	siloxane Dimethyl siloxane
40016	27% solids, 1 part	2000	1,1,1 trichloroethane	Platinum addition	Methyl vinyl siloxane
40021	32% solids, 1 part	500	Xylene	Acetoxy	Dimethyl siloxane
40032	21 % solids, 1 part	800	1,1,1 trichloroethane	Platinum addition	Fluorovinyl methyl siloxane
MED-2213	15% solids, 1 part	7000	1,1,1 trichloroethane		Dimethyl-methyl vinyl siloxane
MED-6400	35% solids, 2 part, 1:1	600	Xylene	Platinum addition	
MED2-6400	25% solids, 2 part, 1:1	800	1,1,1 trichloro-ethane		Vinyl methyl siloxane
MED-6600	35% solids, 2 part	300	Xylene		
MED2-6600		1600	1,1,1 trichloroethane		
MED-6605	30% solids, 1 part	800	Xylene	Acetoxy	
MED3-6605	22% solids, 1 part	1250	1,1,1 trichloroethane		Dimethyl siloxane
MED-6607	33% solids, 1 part	5500	VM&P naphtha	Oxime	
MED-6640	25% solids, 2 part	7000	Xylene		Methyl vinyl siloxane
MED2-6640	15% solids, 2 part	5000	1,1,1 trichloroethane	Platinum addition	
MED2-6650	20% solids, 2 part	3000			Fluorovinyl methyl siloxane
Q7-263010% solids		-	Q7-2650	Acetoxy	Dimethyl siloxane

Table 4.11 Typical Properties of Silicone Elastomeric Adhesives

		Property					
		Specific gravity	Durometer hardness Shore	Tensile strength, Psi	Elongation, Percent	Tear strength, die B, pli	Adhesive strength (to silicone) Pli
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	ASTM D-624	pli
Applied Silicone	40064						18+
Medical Implant	Medical Grade	1.08	24 A	850	750	70	18
Grade,	RTV Silicone Adhesive						
Applied Silicone Corp.	Medical Grade High Strength RTV Silicone Adhesive			950	770		18
NuSil Silicone, NuSil Technology	MED-1137	1.07	29 A	550	450		
Silastic® Medical Materials	Medical Adhesive A	1.06	29 A	450	400	30	20+
Dow Corning Corp.	355 Medical Grade Pressure Sensitive			1.40			

Product no.	Cure Conditions	Comments
40064	Produces acetic acid. Cures @ RT with atmospheric moisture, 20 to 60% RH.	Bonds silicones to each other and some synthetics, metals.
Medical Grade RTV Silicone Adhesive Medical Grade High Strength RTV Silicone Adhesive	24 hours @ 25°C, aged 24 hours @ RT.	Bonding silicone to polyester, etc. High strength bonds to polyester, nylon, polyurethane and metals.
MED-1137	Produces acetic acid. Cure 3 days @ RT with atmospheric moisture, 20 to 60% RH.	Bonding silicones to each other & some synthetics/metals. When fully cured resembles some conventional silicone elastomers.

(continued)

Table 4.11 (continued)

		Property					
		Specific gravity	Durometer hardness Shore	Tensile strength, Psi	Elongation, Percent	Tear strength, die B, pli	Adhesive strength (to silicone) Pli
Product and Manufacturer	Product no.	ASTM D-792	ASTM D-2240	ASTM D-412	ASTM D-412	ASTM D-624	pli
Medical Adhesive A 355 Medical Grade Pressure Sensitive	Produces acetic acid, requires 50% RH & 7 days to cure. Non-curing dispersion - becomes adhesive as solvent evaporates.			Bonding silicone rubber to itself. Useful for cast films or parts from dispersions. Adheres to skin for use with ileostomy and colostomy appliances.			

4.3 Establishing Equivalence

Specific polymeric materials traditionally used for medical applications have been recently withdrawn from the medical market. Silicone elastomers are among those withdrawn. To maintain continued supply of vital implants, methods of determining equivalence for withdrawn elastomers with new or existing ones has been adopted by the FDA in the form of an FDA Guidance Document.

4.3.1 FDA Guidance document for substitution of equivalent elastomers

The FDA will allow manufacturers to change sources of silicone elastomers (and others) if they can show that the replacement material is ‘not substantially different’ from materials described in existing approved applications. The device manufacturer is still required to certify that the processes of fabrication, cure and sterilization it uses in the manufacture of its device are appropriate for the new material and that the device will perform as intended. Premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 USC 360(k) and 21 CFR 807.81(a)(3)(i), or a supplemental premarket approval application under 21 USC 360(k) section 515 and 21 CFR 814.39 is necessary when change could significantly affect the safety or effectiveness of the device. These submissions are required to be submitted and approved before the device may be marketed with the change.

There are a number of tests necessary for comparison of silicone elastomers as indicated by ‘Guidance for Manufacturers of Silicone Devices Affected by Withdrawal of Dow Corning Silastic® Materials’ (Federal Register, Vol. 58, No. 127, Tuesday, July 6, 1993/ Notices, 36207). They compare the physical, chemical and biological properties of the bulk polymers as they are received from the supplier and also compare the molded elastomer as it exists in the final medical device.

Table 4.12 Biocompatibility of Various Elastomers

			Biocompatibility Status*				
				Intracutaneous Systemic			Skin
Classification	Product and Manufacturer	Product no.	Hemolysis	Pyrogenicity	Injection	Injection	Sensitization
	Santoprene®	281-45	passed	passed	passed	passed	passed
Thermoplastic	Rubber,	281-55	passed	passed	passed	passed	passed
elastomer		281-64	passed	passed	passed	passed	passed
	Advanced	281-73	passed	passed	passed	passed	passed
	Elastomer	281-87	passed	passed	passed	passed	passed
	Systems	283-40	passed	passed	passed	passed	passed
PCCE	Ecdel™ Elastomer,	9965	passed		passed	passed	
copolyester	Eastman Chemical Co.	9966					
elastomer	Biospan® Segmented,						
Polyurethane-	Polyurethane,	Biospan®	passed	passed	passed	passed	passed
based	The Polymer						
elastomers	Technology Group,						
	Inc.						
	Hydrothane™,						
	Poly Medica	Hydrothane™					
	Biomaterials, Inc.						
		MP-5000					
Medicaflex™,		MF-5001		passed	passed	passed	
		MF-5040					
	Advanced Resin	MF-5041					
	Technology	MF-5056					
		MF-5057					

		MF-5062					
	Pellethane™	Pellethane™					
	2363 series,	2363 series		passed	passed	passed	
	Dow Chemical Co.						
	PolyBlend™ 1000 ,	PolyBlend™					
	and PolyBlend™	1000 and					
	1100	PolyBlend™					
	Poly Medica	1100					
	Biomaterials, Inc.						
*Biocompatibility Status**							
Intramuscular				*Tissue Cell*			
Product no.	*10 days*	*30 days*	*90 days*	*Culture*	*Comments*		
281-45							
281-55		passed	passed	passed	Passed USP Class **VI** testing,		
281-64					Tripartite testing, mouse embryo		
281-73					toxicity testing and Ames		
281-87					Mutagenicity testing.		
283-40							
9965				passed			
9966							
Biospan®				passed			

(continued)

Table 4.12 (continued)

Hydrothane™					See text for status.		
MF-5000		passed		passed			
MF-5001		passed		passed	Passed USP Class VI testing.		
MF-5040				passed			
MF-5041		passed		passed			
MF-5056				passed			
MF-5057				passed			
MF-5062							
Peliethane™					Passed USP Class VI testing.		
2363 series		passed		passed	See text for status.		
PolyBlend™					See text for status.		
1000 and							
PolyBlend™							
*Biocompatibility Status**							
Classification	*Product and Manufacturer*	*Product no.*	*Hemolysis*	*Intracutaneous Systemic*			*Skin Sensitization*
				Pyrogenicity	*Injection*	*Injection*	*Sensitization*
Polyurethane based elastomers	Tecoflex® and Tecothane®	EG60A EG80D 1055D 1065D	passed		passed	passed	passed

		1074A	passed		passed	passed	
	Thermedics, Inc.	1075D					
		1085A					
		1095A					
	Texin™,						
		Texin™		passed	passed	passed	
	Miles, Inc.						
Polycarbonate based polyurethanes	Carbothane TM, Thermedics, Inc.	PC-3555D PC-3572D PC-3575A PC-3585A PC-3595A	passed		passed	passed	
	ChronoFlex™ AR,						
	Poly Medica	ChronoFlex™	passed	passed	passed	passed	
	Biomaterials, Inc.	AR					
	Coremer™,	Coremer™					
	Corethane®,	TPE 55D			passed	passed	passed
	and	TPE 75D		passed			
		TPE 80A	passed		passed	passed	passed
	Corhesive™,	Corhesive™,	passed	passed	passed	passed	passed
	Corvita Corp.						
Polypropylene based elastomers	Sarlink® medical grade, DSM Thermoplastic Elastomers, Inc.	Sarlink® medical grade					

(continued)

Table 4.12 (continued)

*Biocompatibility Status**

	Intramuscular			Tissue Cell			
Product no.	10 days	30 days	90 days	Culture	Comments		
EG60A EG80D 1055D 1065D 1074A 1075D 1085A 1095A							
Texin™		passed		passed	Passed USP Class VI testing. See text for status.		
PC-3555D PC-3572D PC-3575A PC-3585A PC-3595A							
ChronoFlex™ AR		passed		passed	Passed USP Class VI testing.		
Coremer™					See text for status.		
TPE 55D	passed	passed	passed	passed			
TPE 75D				passed			
TPE 80A	passed	passed	passed	passed			

Corhesive™	passed	passed	passed	passed			
Sarlink® medical grade					See text for status.		
*Biocompatibility Status**							
Classification	*Product and Manufacturer*	*Product no.*	*Hemolysis*	*Intracutaneous Systemic*			*Skin*
				Pyrogenicity	*Injection*	*Injection*	*Sensitization*
Polyvinyl chloride elastomers	Elastichem™PVC, Geon® PVC, B. F. Goodrich Co. Plastics Co.	Elastichem™PVC, PVC					
Ellay™ PVC	Ellay™ PVC Ellay, Inc. Geon® PVC, B. F. Goodrich Co. Multichem™ PVC, Colorite Plastics Co.	Geon® PVC Multichem™ PVC	passed	passed	passed		
		3300-45 NT					
	Teknor™ PVC,	3300-50 NT					
		3300-55 NT					
	Teknor Apex Co.	3300-60 NT 3300-68 NT 3300-75 NT 3300-80 NT		passed	passed	passed	passed
	Teknor™ PVC,	3300-85 NT 3300-90 NT		passed	passed	passed	passed

(continued)

Table 4.12 (continued)

	Teknor Apex Co.	3310-50 NT 3310-55 NT 3310-60 NT 3310-65 NT 3310-70 NT 3310-75 NT 3310-80 NT 3310-85 NT 3310-90 NT					
		90A471R-60NT		passed	passed	passed	
		90A471R-65NT		passed	passed	passed	
		9OA471R-70NT		passed	passed	passed	
		90A471R-75NT		passed	passed	passed	
		90A471R-80NT		passed	passed	passed	
		90A471R-85NT		passed	passed	passed	
		90A471R-90NT		passed	passed	passed	
*Biocompatibility Status**							
	Intramuscular			*Tissue Cell*			
Product no.	*10 days*	*30 days*	*90 days*	*Culture*	*Comments*		
Elastichem™					See text for status.		
PVC							
Ellay™ PVC		passed		passed	Passed USP Class VI testing.		
Geon® PVC					See text for status.		
Multichem™					See text for status.		
PVC							

3300-45 NT				passed			
3300-50 NT				passed			
3300-55 NT				passed			
3300-60 NT				passed			
3300-68 NT				passed			
3300-75 NT				passed			
3300-80 NT		passed		passed	Passed USP Class VI testing.		
3300-85 NT				passed	Passed USP Class VI testing.		
3300-90 NT				passed			
3310-50 NT				passed			
3310-55 NT				passed			
3310-60 NT				passed			
3310-65 NT				passed			
3310-70 NT				passed			
3310-75 NT				passed			
3310-80 NT				passed			
3310-85 NT				passed			
3310-90 NT				passed			
90A471R-60NT		passed			Passed USP Class VI testing.		
90A471R-65NT		passed			Passed USP Class VI testing.		

(continued)

Table 4.12 (continued)

90A471R-70NT		passed			Passed USP Class VI testing.		
90A471R-75NT		passed			Passed USP Class VI testing.		
90A471R-80NT		passed			Passed USP Class VI testing.		
90A471R-85NT		passed			Passed USP Class VI testing.		
90A471R-90NT		passed			Passed USP Class VI testing.		
*Biocompatibility Status**							
Classification	*Product and Manufacturer*	*Product no.*	*Hemolysis*	*Intracutaneous Systemic*			*Skin*
				Pyrogenicity	*Injection*	*Injection*	*Sensitization*
		R70-001	passed	passed	passed	passed	
Styrene-based elastomers	C-Flex®,	R70-003	passed	passed	passed	passed	
		R70-005	passed	passed	passed	passed	
	Consolidated Polymer Technologies, Inc.	R70-026	passed	passed	passed	passed	
		R70-028	passed	passed	passed	passed	
		R70-046	passed	passed	passed	passed	
		R70-050	passed	passed	passed	passed	
		R70-051	passed	passed	passed	passed	
		R70-058	passed	passed	passed	passed	

		R70-067	passed	passed	passed	passed	
		R70-068	passed	passed	passed	passed	
		R70-072	passed	passed	passed	passed	
		R70-081	passed	passed	passed	passed	
		R70-082	passed	passed	passed	passed	
		R70-085	passed	passed	passed	passed	
		R70-089	passed	passed	passed	passed	
		R70-091	passed	passed	passed	passed	
		R70-116	passed	passed	passed	passed	
		R70-190	passed	passed	passed	passed	
		R70-214	passed	passed	passed	passed	
		D-2103	passed	passed	passed	passed	
	Kraton®,	D-2104	passed	passed	passed	passed	
		D-2109	passed	passed	passed	passed	
	Shell	G-2701	passed	passed	passed	passed	
	Chemical Co.	G-2703	passed	passed	passed	passed	
		G-2705	passed	passed	passed	passed	
		G-2706	passed	passed	passed	passed	
		G-2712	passed	passed	passed	passed	
*Biocompatibility Status**							
	Intramuscular			*Tissue Cell*			
Product no.	*10 days*	*30 days*	*90 days*	*Culture*	*Comments*		
R70-001	passed	passed	passed	passed			
R70-003	passed	passed	passed	passed	C-Flex testing data is available from		
R70-005					manufacturer.		
R70-026	passed	passed	passed	passed			

(continued)

Table 4.12 (continued)

R70-028	passed	passed	passed	passed			
R70-046	passed	passed	passed	passed			
R70-050	passed	passed	passed	passed			
R70-051	passed	passed	passed	passed			
R70-058	passed	passed	passed	passed			
R70-067	passed	passed	passed	passed			
R70-068	passed	passed	passed	passed			
R70-072	passed	passed	passed	passed			
R70-081	passed	passed	passed	passed			
R70-082	passed	passed	passed	passed			
R70-085	passed	passed	passed	passed			
R70-089	passed	passed	passed	passed			
R70-091	passed	passed	passed	passed			
R70-116	passed	passed	passed	passed			
R70-190	passed	passed	passed	passed			
R70-214	passed	passed	passed	passed			
D-2103	passed	passed	passed	passed			
D-2104	-	passed	-	passed	Passed USP Class VI testing.		
D-2109		passed		passed	Passed USP Class VI testing.		
G-2701		passed		passed	Passed USP Class VI testing.		

G-2703		passed		passed	Passed USP Class VI testing.		
G-2705		passed		passed	Passed USP Class VI testing.		
G-2706		passed		passed	Passed USP Class VI testing.		
G-2712		passed		passed	Passed USP Class VI testing.		
*Biocompatibility Status**							
Classification	*Product and Manufacturer*	*Product no.*	*Hemolysis*	*Intracutaneous Systemic*			*Skin*
				Pyrogenicity	*Injection*	*Injection*	*Sensitization*
Polydimethylsiloxane	Applied Silicone Medical Implant Grade, Applied Silicone Corp.	Applied Silicone Medical Implant Grade					
	NuSii Silicone, NuSil Technology	NuSii Silicone					
		MDX4-4210		passed	passed	passed	passed
	Silastic ®	Q7-4535	passed	passed	passed	passed	
	Medical Materials,	Q7-4550	passed	passed	passed	passed	
		Q7-4565	passed	passed	passed	passed	
	Dow Corning Corp.	Q7-4720	passed	passed	passed	passed	
		Q7-4735	passed	passed	passed	passed	
Polydimethyl	Silastic ®	Q7-4750	passed	passed	passed	passed	

(continued)

Table 4.12 (continued)

siloxane	Medical Materials,	Q7-4765	passed	passed	passed	passed	
		Q7-4780	passed	passed	passed	passed	
	Dow Corning Corp.	Q7-4840	passed	passed	passed	passed	
		Q7-4850	passed	passed	passed	passed	
		Q7-6860	passed	passed	passed	passed	passed
		Medical					
		Adhesive A		passed	passed	passed	passed
		355 Medical		passed	passed	passed	passed
		Grade Pressure					
		Sensitive					
*Biocompatibility Status**							
	Intramuscular			*Tissue Cell*			
Product no.	*10 days*	*30 days*	*90 days*	*Culture*	*Comments*		
Applied Silicone					Applied Silicone testing data is available from manufacturer.		
Medical							
Implant							
Grade							
NuSii Silicone					See text for status.		
MDX4-4210	passed	passed		passed	See text for status.		
Q7-4535	passed	passed			See text for status.		

Q7-4550	passed	passed			See text for status.		
Q7-4565	passed	passed			See text for status.		
Q7-4720				passed	See text for status.		
Q7-4735	passed		passed		See text for status.		
Q7-4750	passed				See text for status.		
Q7-4765	passed				See text for status.		
Q7-4780	passed				See text for status.		
Q7-4840	passed				See text for status.		
Q7-4850		passed		passed	See text for status.		
Q7-6860	passed				See text for status.		
Medical Adhesive A					See text for status.		
	passed	passed	passed		See text for status.		
355 Medical	passed	passed	passed	passed	See text for status.		
Grade Pressure Sensitive							

*Biocompatibility based on comparison with USP negative controls
Note: It is the user's responsibility to adequately test or determine that these materials are suitable or safe for any application.

Table 4.13 Sterilization Methods for Elastomers

Product	Steam/autoclave	Cobalt 60	Ethylene oxide	Cold solution
Biospan	OK	—	OK	—
Biospan D	—	—	—	
Biospan S	—	—	—	—
C-Flex R70-001	OK	OK	OK	—
R70-003	OK	OK	OK	—
R70-005	no	OK	OK	—
R70-026	OK	no	OK	—
R70-028	no	OK	OK	—
R70-046	no	OK	OK	—
R70-050	OK	OK	OK	—
R70-051	OK	OK	OK	—
R70-072	OK	OK	OK	OK
R70-081	OK	OK	OK	—
R70-082	OK	OK	OK	—
R70-085	OK	OK	OK	—
R70-089	NR	OK	OK	—
R70-091	NR	OK	OK	—
R70-116	no	OK	OK	—
R70-190	no	OK	OK	
R70-214	no	OK	OK	—
Carbothane	with caution	—	OK	—
ChronoFlex	—	—	—	—
Coremer	—	OK	OK	OK
Corethane 80A	—	OK	OK	OK
55D	—	OK	OK	OK
75D	—	OK	OK	OK
Corhesive	—	—	—	—
Ecdel elastomers	OK	no	OK	—
Hydrothane		—	—	
—				
Kraton G-series	—	OK		
D-series	—	—	OK	
Medicaflex	no	OK	OK	—
Natural rubber, gum	OK	OK	OK	
Natural rubber, latex	with caution	OK	OK	—
Pellethane	no	OK	OK	—
Poly blend	—		—	”
Poly blend 1100		—	—	—
PVC Elastichem	OK	OK	OK	—
Ellay	OK	OK	OK	—
Geon	—	—	—	
Multi-Chem	OK	OK	OK	—
Teknor	OK	OK	OK	—

(continued)

Table 4.13 (continued)

Product	Steam/autoclave	Cobalt 60	Ethylene oxide	Cold solution
in general	Flexible	with caution	OK	—
	PVC, OK			
	rigid PVC, no			
Santoprene	OK	OK	OK	OK
Sarlink 3260	—			—
Silicone High consistency	OK	OK	OK	—
LIM	OK	OK	OK	—
Adhesives	OK	OK	OK	—
Dispersions	OK	OK	OK	—
Tecoflex	with caution	OK	OK	with caution
Tecothane	—	OK	OK	with caution
Texin	no	OK	OK	—

Caution: with some aromatic polyurethanes methylene dianiline (MDA) can be generated with steam sterilization.

Table 4.14 Water Absorption of Various Elastomers

Classification	Product and manufacturer	Product no.	Water absorption, percent (after 24 hours) ASTM-D 570
Thermoplastic vulcanizate	Santoprene® Rubber,	281-55 281-64	6.0
	Advanced Elastomer Systems	281-87 283-40	0.0
PCCE	Ecdel™ Elastomer,	9965	
copolyester		9966	0.4
elastomer	Eastman Chemical Co.	9967	
	Corethane®,	TPE 80A	1.2
Polycarbonate-based	Corvita Corp.	TPE 55D TPE 75D	0.9 0.8
polyurethanes	Corhesive™,		1.2
	Corvita Corp.		
	Biospan® segmented	Biospan®	1.5
Polyurethane-based	polyurethane, The Polymer Technology	Biospan®D Biospan®S	1.3 1.5
elastomers	Group, Inc.		
	PolyBlend™ 1000,	PB1000-650	<
	and		
	PolyBlend™ 1100	PB1100-55	
		PB1100-60	<0.4
	Poly Medica	PB1100-75	
	Biomaterials, Inc.	PB1100-80	
Silicone rubber			0.1-0.5
Silicone type A adhesive			<0.2

4.3.2 Equivalent silicone elastomers

Two manufacturers, NuSil Technology and Applied Silicone Corp., are providing equivalent silicone materials for the Dow Corning products that have been withdrawn. Tables 4.15 and 4.16 gives reported comparisons.

Table 4.15 Equivalent Silicone Elastomers for Existing Dow Corning Silicones

Dow Corning Silicone*	NuSilt‡ *Silicone Equivalent*	Applied Δ *Silicone Equivalent*	Medical Grade Silicone Description
Medical	MED-1137	40064	Medical RTV Adhesive, Acetoxy
Adhesive A			System (see also Rehau, Table 4.16)
Q7-4535	MED-4535	40044	High Consistency, 35 Durometer, Peroxide Cure
Q7-4550	MED-4550	40045	High Consistency, 50 Durometer, Peroxide Cure
Q7-4565	MED-4565	40046	High Consistency, 65 Durometer, Peroxide Cure
Q7-4720	MED-4720	40043	High Consistency, 20 Durometer, Platinum Cure
Q7-4735	MED-4735	40039	High Consistency, 35 Durometer, Platinum Cure
Q7-4750	MED-4750	40040	High Consistency, 50 Durometer, Platinum Cure
Q7-4780	MED-4780	40042	High Consistency, 80 Durometer, Platinum Cure
MDX4-4210	MED-42111	40072	Liquid Silicone, 25 Durometer, Platinum Cure
		40029	Liquid Silicone, 30 Durometer, Platinum Cure
Q7-4840	MED-4840	40026	Liquid Silicone, 40 Durometer Platinum Cure
Q7-4850	MED-4850	40027	Liquid Silicone, 50 Durometer, Platinum Cure
Q7-4865	MED-4865		Liquid Silicone, 65 Durometer, Platinum Cure
DC-360	MED-360	40047	Medical Grade Silicone Fluid, 1000 cps.
	Specify	40073	Medical Grade Silicone Fluid, 350 cps.
	viscosity	40074	Medical Grade Silicone Fluid, 20 cps.

* Dow Corning Corp., Midland, Ml. ‡ NuSil Silicone Technology, Carpinteria, CA
Δ Applied Silicone Corp., Ventura, CA Note: It is the user's responsibility to adequately test or determine that these materials are suitable or safe for any application.

Table 4.16 Equivalent Silicone Elastomers for Withdrawn Dow Corning silicones

Dow Corning Silicone*	NuSilt‡ *Silicone Equivalent*	Applied ∆ *Silicone Equivalent*	Medical Grade Silicone Description
MDX4-4515	MED-4515	40045	50 Durometer, peroxide cure
MDX4-4516	MED-4516	40046	60 Durometer, peroxide cure
Q7-2245	MED-2245	40009	40 Durometer, platinum cure
Q7-2213	MED-2213	40076	Dispersion in 1, 1, 1 trichloroethane
Rehau 1511¥		40076	Medical RTV adhesive, acetoxy system

*Dow Corning Corp., Midland, Ml. ‡ NuSil Silicone Technology, Carpinteria, CA.
△ Applied Silicone Corp., Ventura, CA. ¥ Rehau AG and Co., Rehau, Germany.
Note: It is the user's responsibility to adequately test or determine that these materials are suitable or safe for any application.

4.4 Sterilization of Elastomers

4.4.1 Sterilization methods

Not all materials respond alike when subjected to various means of sterilization. Some are heat sensitive, some will absorb sterilization fluids, some will be affected by molecular changes when subjected to radiation sterilization and others will absorb and hold irritating gases for extended periods of time. Table 4.13 gives sterilization methods that have been judged most appropriate for each elastomer. The consequences of using an inappropriate method can be loss in physical properties and an adverse biological response.

4.5 Relevant ASTM Standards

Standard methods of testing elastomers used for medical applications are given by specific ASTM test methods. Physical and biological tests are provided here to serve as references for the data cited in the tables and listed in Table 4.17. They are also designated in the FDA Guidance Document.

4.6 Biocompatibility

Table 4.12 on biocompatibility of various elastomers is intended to show the status of *in vitro* and *in vivo* testing. The successful outcome of these tests can serve as guides to potentially acceptable performance of an elastomeric product in a medical device under development. However, the use of elastomeric products in medical devices is the responsibility of the device manufacturer who must establish their safety and efficacy with the FDA.

Table 4.17 Relevant ASTM Standards

D 395	Test Method for Rubber Property - Compression Set
D 412	Test Method for Vulcanized Rubber, Thermoplastic Rubbers and Thermoplastic Elastomer - Tension
D 471	Test Method for Rubber Property - Effect of Liquids
D 570	Test Method for Water Absorption of Plastics
D 624	Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomer
D 638	Test method for Tensile Properties of Plastics
D 792	Test Method for Specific Gravity (Relative Density) and Density of Plastics by Displacement
D 797	Test Methods for Rubber Property - Young's Modulus at Normal and Subnormal Temperatures
D 1630	Test Method for Rubber Property - Abrasion Resistance (NBS Abrader)
D 1708	Test method for Tensile Properties of Plastics by Use of Microtensile Specimens
D 1790	Test method for Brittleness Temperature of Plastic Film by Impact
D 1938	Test method for Tear Propagation Resistance of Plastic Film and Thin Sheeting by a Single-Tear Method
D 2240	Test Method for Rubber Property - Durometer Hardness
D 2702	Standard Practice for Rubber Chemicals - Determination of Infrared Absorption Characteristics
D 3418	Test Method for Transition Temperatures of Polymers by Thermal Analysis
D 3593	Test Method for Molecular Weight Averages and Molecular Weight Distribution of Certain Polymers by Liquid Size-Exclusion Chromatography (Gel Permeation Chromatography, GPC) Using Universal Calibration
D 5023	Test Method for Measuring the Dynamic Mechanical Properties of Plastics Using Three Point Bending
D 5026	Test Method for Measuring the Dynamic Mechanical Properties of Plastics in Tension
E 355	Standard Practice for Gas Chromatography, Terms and Relationships
E 1356	Test Method for Glass Transition Temperatures by Differential Scanning Calorimetry or Differential Thermal Analysis
F 604	Classification for Silicone Elastomers Used in Medical Applications
F 619	Standard Practice for Extraction of Medical Plastics
F 720	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test
F 748	Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices
F 749	Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit
F 750	Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse
F 813	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
F 895	Standard Practice for Agar Diffusion Cell Culture Screening for Cytotoxicity
F 981	Standard Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone

4.7 Sources

- AlphaGaryAlphaGary, Leominster, MA
- Applied SiliconeApplied Silicone Corp., Ventura, CA
- Biospan®Polymer Technology Group, Inc., Emeryville, CA
- C-Flex®Consolidated Polymer Technologies, Inc., Largo, FL
- Carbothane™Thermedics, Inc., Woburn, MA
- ChronoFlex™PolyMedica Industries, Inc., Woburn, MA
- Coremer™Corvita Corp., Miami, FL
- Corethane®Corvita Corp., Miami, FL
- Corhesive™Corvita Corp., Miami, FL
- Ecdel™Eastman Chemical Co., Kingsport, TN
- Elastichem™Colorite Plastics Co., Ridgefield, NJ
- Ellay™Ellay, Inc., City of Commerce, CA
- Geon®B.F. Goodrich Co., Chemical Group, Cleveland, OH
- Hydrothane™PolyMedica Industries, Inc., Woburn, MA
- Kraton®Shell Chemical Co., Oak Brook, IL
- Medicaflex™Advanced Resin Technology, Manchester, NH
- Multichem™Colorite Plastics Co., Ridgefield, NJ
- Natural rubberExxon Chem. Co., Buffalo Grove, IL Goodyear Tire and Rubber Co., Akron, OH
- NuSil SiliconeNuSil Technology, Carpinteria, CA
- Pellethane™Dow Chemical Co., Midland, MI
- PolyBlend™PolyMedica Industries, Inc., Woburn, MA
- Santoprene®Advanced Elastomer Systems, St Louis MO
- Sarlink®DSM Thermoplastic Elastomers, Inc., Leominster, MA
- SilasticDow Corning Corp., Midland, MI
- Tecoflex®Thermedics, Inc., Woburn, MA
- Tecothane®Thermedics, Inc., Woburn, MA
- Teknor™Teknor Apex Co., Pawtucket, RI
- Texin™Miles, Inc., Pittsburgh, PA