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Standard Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices¹

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1. Scope

1.1 This terminology covers polymeric biomaterials in medical and surgical devices. Terms are defined as they are used relative to medical and surgical materials and devices. Terms that are generally understood and in common usage or adequately defined in other readily available references are not included except where particular delineation to biomaterials may be more clearly stated.

1.2 This terminology is therefore intended to be selective of terms used generally in materials science and technology and published in a number of documents, such as those listed in the succeeding sections. The listing is also intended to define terms that appear prominently within other ASTM standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published in other ASTM standards on metals, ceramics and glass, rubbers and polymers, and so forth, or published by other standards writing organizations, such as International Standards Organization (ISO), American Institute of Mechanical Engineers (AIME), American Society of Plastic and Reconstructive Surgeons (ASPR), and Tissue Culture Association (TCA).

1.4 A need exists for this terminology to supplement current documents on terminology which concentrate on materials. This terminology covers each of the following disciplines: plastics (polymers), rubber (elastomers), and textiles (polymer derived).

1.5 An increasing number of product (polymeric, metallurgical, and ceramic types) designations and designations for chemical, physical, mechanical, and analytical tests and standards are coming into common usage in the literature and commerce of biomaterials in medical and surgical devices and clinical services. Section 2 lists those documents referenced in this terminology.

1.6 Table 1 lists abbreviated, anagramic designations. Annex A1 is a thesaurus of general usage terms relating to biomaterials.

2. Referenced Documents

2.1 *ASTM Standards*:²

- D638 Test Method for Tensile Properties of Plastics
- D747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam
- D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
- D882 Test Method for Tensile Properties of Thin Plastic Sheeting
- D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics
- SI 10–02 American National Standard for Use of the International System of Units (SI): The Modern Metric System

3. Terminology

3.1 *Definitions*:

acetal plastic, *n*—a plastic based on polymers having a predominance of acetal linkages in the main chain. (See also polyoxymethylene.) **D20**

acrylic plastic, *n*—a plastic based on polymers made with acrylic acid or a structural derivative of acrylic acid. **D20**

addition polymerization, *n*—polymerization in which monomers are linked together without the splitting off of water or other simple molecules and involves the opening of a double bond. **D20**

aging, *n*—the process of exposing materials to an environment for an interval of time. **D20**

aging effect, *n*—a change in a material brought about by exposure of the material to an environment for an interval of time.

alkyd resin, *n*—a polyester convertible into a crosslinked form; requiring a reactant of functionality higher than two, or having double bonds. **D20**

apparent density—see **density, apparent**.

artificial weathering, *n*—exposure of a material to laboratory conditions that simulate outdoor weathering.

DISCUSSION—Exposure conditions may be cyclic, involving changes

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

TABLE 1 Abbreviated, Anagramic Designations—Acronyms^{A,B}

Term	Classification	Descriptive Term in Full
AAS	analytic, chemical	atomic absorption spectroscopy
ABC	plastic, polymer	acryline bone cement
ABS	plastic, polymer	acrylonitrile-butadiene-styrene polymer
AN	polymer, monomer	acrylonitrile
ATR-IR	analytic, chemical	attenuated total reflectance—infrared
CA	plastic, polymer	cellulose acetate (sheet X ray)
CAB	plastic, polymer	cellulose acetate-butyrate
CP	plastic, polymer	cellulose propionate or cellulose acetate-propionate
DSC	analytic, physical	differential scanning calorimetry
DTA	analytic, physical	differential thermal analysis
EDTA	analyses	ethylene dinitrilo tetraacetic acid
EPM/EPDM	elastomer	ethylene-propylene terpolymer
EPR	elastomer	see EPM/EDPM above
ESCA	analytic, chemical	used for X-ray photoelectron spectroscopy
ETFE	analytic, chemical	(ethylene-tetrafluoroethylene-fluoroplastics)
FEP	plastics, polymers	perfluoro(ethylene-propylene) copolymer
GC	analytic, chemical	gas chromatography
HEMA	plastic, polymer	hydroxyethyl methacrylate (polymer)
HPLC	analytic, chemical	high performance liquid chromatography
IR	analytic, physical	infrared spectroscopy (for example, IR scan)
kPa	mechanical, physical	kiloPascal (unit of pressure—see Practice SI 10-02, Appendix)
MPa	mechanical, physical	megaPascal (unit of pressure—see Practice SI 10-02, Appendix)
MW (mw)	physical, molecular	molecular weight
MWD (mwd)	physical, molecular	molecular weight distribution (see mw, above)
MRI	clinical	magnetic resonance imaging (diagnostic application of nmr)
MRS	analytic, chemical	magnetic resonance spectroscopy (diagnostic application of nmr)
NBR	elastomer, polymer	nitrile-butadiene rubber
NMR (nmr)	analytic, physical	nuclear magnetic resonance
PB	elastomer, polymer	polybutylene
PC	plastic, polymer	polycarbonate
PCTFE	plastic, polymer	polychlorotrifluoroethylene
PDMS	elastomer, polymer fluid	silicone, polydimethyl siloxane
PE	plastic, polymer	polyethylene
PET	plastic, polymer	poly(ethylene terephthalate)
PFA	plastic, polymer	perfluoroalkoxy fluorocarbon polymer
PMMA	plastic, polymer	poly(methyl methacrylate)
PTFE	plastic, polymer	polytetrafluoroethylene
PU	plastic or elastomer polymer	polyurethane
PVA	plastic, polymer	poly(vinyl alcohol) (often poly(vinyl acetate))
PVAc	plastic, polymer	poly(vinyl acetate)
PVC	plastic, polymer	poly(vinyl chloride)
PVDC	plastic, polymer	poly(vinylidene chloride)
PVP	polymer	poly(vinyl pyrrrolidone)
RTV	elastomer, plastic	room temperature vulcanization
SAN	elastomer, polymer	styrene-acrylonitrile polymer
SB	elastomer, polymer	styrene-butadiene polymer
SEM	analytic, microscopy	scanning electron microscopy (cf TEM)
SR	elastomer, polymer	styrene rubber (elastomer)
TEM	analytic, microscopy	transmission electron microscopy (cf SEM)
TAR	device or prosthesis	total ankle replacement
TER	device or prosthesis	total elbow replacement
THR	device or prosthesis	total hip replacement
TJR	device or prosthesis	total joint replacement
TKR	device or prosthesis	total knee replacement
TSR	device or prosthesis	total shoulder replacement
TWR	device or prosthesis	total wrist replacement
UHMW	plastic, polymer	ultrahigh molecular weight polyethylene (stated polymer)
UMHWPE	plastic, polymer	ultrahigh molecular weight polyethylene (see UHMW)
UV	analytic, physical	ultraviolet light spectroscopy
VCM	polymer, monomer	vinyl chloride monomer content
XPS	analytic, chemical	X-ray photoelectric spectroscopy (also called ESCA)
XRD	analytic, physical	X-ray diffraction

^A If a method or name is used for the first time in a text (paper, etc.), it must be presented in full with the abbreviation in brackets.

^B If the text is long or consists of several chapters, the full name must be repeated in reasonable sequences, at least when first mentioned in a new chapter.

in temperature, relative humidity, radiant energy, and many other elements found in the atmosphere in various geographical areas. The laboratory exposure conditions are usually intensified beyond those encountered in actual out-door exposure to accelerate the effect.

D20

blister, n—in sheet plastics, an imperfection, a rounded elevation of the surface, with boundaries that may be more or less

sharply defined, somewhat resembling in shape a blister on the human skin. **D20**

block copolymer, n—an essentially linear copolymer in which there are repeated sequences of polymeric segments of different chemical structure. **D20**

bloom, n—a visible exudation or efflorescence of a performance additive on the surface of a material. **D20**

bulk density—the weight per unit volume of a material including voids inherent in the material as tested.

DISCUSSION—This term is sometimes used synonymously with apparent density.

bulk factor, *n*—the ratio of the volume of a given mass of molding material to its volume in the molded form.

DISCUSSION—The bulk factor is also equal to the ratio of the density of the material to its apparent density in the unmolded form. **D20**

ISO

butylene plastic—plastic based on resins made by the polymerization of butene or copolymerization of butene with one or more unsaturated compounds, the butene being in greatest amount by weight. **D20**

cast film, *n*—a film made by depositing a layer of plastic, either molten, in solution, or in a dispersion, onto a surface, solidifying the deposit and removing the film from the surface. **D20**

cell, *n*—a small partially or completely enclosed cavity. **D20**

cell, closed—see **closed cell**.

cell, open—see **open cell**.

chemically foamed polymeric material, *n*—a cellular material in which the cells are formed by gases generated by thermal decomposition or other chemical reaction. **D20**

chlorofluorocarbon plastic, *n*—a plastic based on polymers made with monomers composed of chlorine, fluorine, and carbon only. **ISO**

chlorofluorohydrocarbon plastic, *n*—a plastic based on polymers made with monomers composed of chlorine, fluorine, hydrogen, and carbon only. **ISO**

closed cell, *n*—a cell totally enclosed by its walls and hence not interconnecting with other cells. (See also **cell** and **open cell**.) **ISO**

closed-cell foamed plastic, *n*—a plastic in which almost all the cells are noninterconnecting. **D20**

cold flow—see preferred term **creep**.

compression molding, *n*—a process for molding a material in a confined cavity by applying pressure and usually heat. **D20**

condensation polymer, *n*—polymerization in which during an acid/base reaction a small molecule is often split out.

copolymer, *n*—a polymer consisting of molecules characterized by the repetition (neglecting ends, branch junctions and other irregularities) of two or more different types of monomeric units. See **polymer**. **D20**

copolymerization—see **polymerization** and **copolymer**.

crazing, *n*—apparent fine cracks at or under the surface of a plastic.

DISCUSSION—The crazed areas are composed of polymeric material of lower density than the surrounding matrix.

creep, *n*—the time-dependent part of strain resulting from stress.

cure, *v*—to change the properties of a polymeric system into a more stable, usable condition by the use of heat, radiation, or reaction with chemical additives.

DISCUSSION—Cure may be accomplished, for example, by removal of solvent or crosslinking. **ISO**

degradation, *n*—a deleterious change in the chemical structure, physical properties, or appearance of a plastic.

density, apparent, *n*—the weight in air of a unit of volume of a material.

DISCUSSION—This term is sometimes used synonymously with bulk density.

density, bulk, *n*—the weight in air of a unit of volume of a material.

DISCUSSION—This term is commonly used synonymously with apparent density (1973). **D20**

elastomer, *n*—a macromolecular material that at room temperature returns rapidly to approximately its initial dimensions and shape after substantial deformation by a weak stress and release of the stress. **D20**

epoxy plastic, *n*—a thermoplastic or thermosetting plastic containing ether or hydroxyalkyl repeating units, or both, resulting from the ring-opening reactions of lower-molecular weight polyfunctional oxirane resins, or compounds, with catalysts or with various polyfunctional acidic or basic coreactants.

DISCUSSION—Epoxy plastics often are modified by the incorporation of diluents, plasticizers, fillers, thixotropic agents, or other materials. **D20**

ethylene plastic—a plastic based on polymers of ethylene or copolymers of ethylene with other monomers, the ethylene being in greatest amount by mass. **ISO**

filler, *n*—a relatively inert material added to a plastic to modify its strength, performance, working properties, or other qualities, or to lower costs. (See also **reinforced plastic**.)

film, *n*—in plastics, term for sheeting having a nominal thickness not greater than 0.25 mm (0.01 in.). (See also **sheeting**.)

fluorocarbon plastic, *n*—a plastic based on polymers made with monomers composed of fluorine and carbon only.

DISCUSSION—When the monomer is essentially tetrafluoro-ethylene, the prefix TFE may be used to designate these materials. When the resins are copolymers of tetrafluoro-ethylene and hexafluoropropylene, the resins may be designated with the prefix FEP. Other prefixes may be adopted to designate other fluorocarbon plastics. **ISO**

fluorohydrocarbon plastic, *n*—a plastic based on polymers made with monomers composed of fluorine, hydrogen, and carbon only. **ISO**

fluoroplastic, *n*—a plastic based on polymers with monomers containing one or more atoms of fluorine or copolymers of such monomers with other monomers, the fluorine-containing monomer(s) being in greatest amount by mass. (See also **fluorocarbon plastic**, **chlorofluorocarbon plastic**, **fluorohydrocarbon plastic**, and **chlorofluorohydrocarbon plastic**.)

gel, *n*—*in polymer*, a semisolid system consisting of a network of solid aggregates in which liquid is held.