Materials Selection for Medical Electronics

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Insulating and jacketing material options for wire and cable are innumerable, even if the field is narrowed to those with some qualification for use in medical electronics. Factors that contribute to materials selection decisions include biocompatibility, disinfection and sterilization compatibility, revision control assurance, environmental regulatory compliance, aesthetics, flexibility, durability, and cost. Subtle differences in priority may result in significant differences in product design. Suppose, for example, an electrosurgical cable requires flexibility, biocompatibility, gas plasma sterilization compatibility, and durability. The jacket material selection may be a polyurethane alloy. However, if maximum flexibility is required, or if a smooth texture that allows the cable to easily slip along contact surfaces is a priority – the jacket material selection may be parylene coated silicone rubber. NEWTuf® reinforced silicone jackets offer superior axial strength for cables that will be repeatedly wiped during cleaning and disinfection procedures. NEWTC can incorporate both the NEWtuf® reinforcement and parylene coating features to a silicone jacket without increasing the size compared to a standard silicone or TPE jacket for the same electrosurgical cable.

Biocompatibility and defining “Medical” Grade

Biocompatibility is ultimately a function of a completed device including all of its components, assembly processes and overall design. However, thoughtful material selection will help contribute to an overall product assurance. Material suppliers may describe their products as suitable for food contact, or having passed testing for ISO 10993-5 (cytotoxicity), or select other sections. Some maintain drug master files (DMF) at the FDA with confidential details about formulations and processes that can be used in support of a device application. Some suppliers offer parallel product lines – one for industrial products and one for medical devices. Chemistry and performance of the two material families may be essentially the same, though the medical suite of materials will have specific revision controls in place, documentation and certifications will accompany each shipment, and price will reflect the additional services. Each level of qualification is intended for different applications defined by device type (surface, external communicating, implant) and contact duration (limited, prolonged, or permanent). It is essential to define your application requirements at the design phase to avoid material changes later. Likewise, it is important to avoid over specifying biocompatibility requirements as each level of assurance activities has an associated cost.

USP VI and ISO 10993

Prior to 1995, the United States Pharmacopoeia referred US device manufacturers to the Tripartite Biocompatibility Guidance Document for classification of plastics based on biological response in mice and rabbits to various injection and implantations of extractions and material samples. “USP Class VI” included the full range of injection and implantation studies, and it was not uncommon for material suppliers pursuing medical markets to have their materials tested against these criteria. This enabled device design teams to use the USP classification as a materials selection reference. It did *not,* however, guaranty that a completed device would pass the same tests or those device manufacturers could avoid testing. Subsequent processes, adhesives, printing, packaging, sterilization and other final preparations all contribute to final device performance thus must be considered in specific tests to determine the suitability of a material for its intended use.

In May 1995 the US FDA began referring to ISO 10993-1 for new device submissions. The ISO standard includes a table that defines devices by contact type and duration. Tests for biological response are then specified according to the resulting category. Although the ISO standard was intended to harmonize device testing requirements, the US FDA and Japanese Ministry of Health, Labor and Welfare (MHLW) have made certain modifications and may require testing above and beyond what is indicated by the test selection guidance table. In all cases, the standard is intended to offer guidance rather than an exclusive checklist for qualification.

While USP and ISO categories, classes and test protocols do not specifically match, it continued to be common for material suppliers and design engineers to use USP as a reference and selection criteria until relatively recently. Current design efforts focus on ISO 10993. The 20 sections of the ISO standard cover topics such as test selection, sample preparation, specific methods, animal welfare requirements, degradation products testing and others. It is not uncommon to see material suppliers reference ISO 10993 in their product literature, but it is essential to know what they are claiming, and whether that will be helpful or necessary in your device design and material selection process.

Selecting materials using biocompatibility claims

Cytotoxicity testing (ISO 10993-5) is a comparatively quick and inexpensive test commonly used for materials screening or comparisons. Cytotoxicity, Sensitization and Irritation (ISO 10993-10) tests are required for all device categories defined by ISO 10993-1. The field of “innumerable material options” begins to narrow as one specifies additional testing and test frequency, but there are still many high performance insulation and jacket materials that have passed ISO 10993-5 and -10 at least on a one-time basis for material selection purposes.

Bracket testing is another practice that materials suppliers use (and actually, ISO suggests) to minimize animal testing and duplication of effort. Compounders for example, will conduct one-time tests of representative formulations that bracket a material family (for example, using the same ingredients in different proportions to achieve a range of hardness or flexibility). Device designers may then select materials with optimum physical performance from the entire range of materials based on the representative tests and knowledge of their own application and intended use.

	biocompatibility	glossy	Matte	Clear / translucent	Opaque	NEWTC Custom Colors	flame resistance	flexibility	fluid resistant	halogen free	heat resistance	high voltage	low smoke	small - thin - micro	toughness (tear, abrasion)
PVC	●	●	●	●	●	●	●	●	●		●			●	●
PE	●	●			●	●			●	●				●	●
PP	●	●			●	●	●		●	●				●	●
PA	●	●		●	●				●	●	●			●	●
TPU	●	●	●	●	●	●	●	●	●	●	●		●	●	●
SR	●	●	●	●	●	●	●	●	●	●	●	●		●	
ETFE	●	●	●	●	●		●		●		●	●	●	●	●
PFA	●	●	●	●	●		●		●		●	●	●	●	●
FEP	●	●	●	●	●		●		●		●	●	●	●	●
TPE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
COPE	●	●		●	●		●		●	●	●			●	●
PEEK	●	●		●	●		●		●	●	●		●	●	●

NEWTC offers a full selection of specialty materials for medical electronics with various levels of biocompatibility to match your specifications

Designing for Sterilization Compatibility

Similarly, material compatibility with sterilization methods should be considered at the earliest design phases and confirmed in prototype and qualification processes. As with biocompatibility requirements, communicating expectations with cable design engineers that are familiar with a wide range of thermoplastics, thermosets, coatings, sterilization techniques, caveats, modes of failure and other topics will lead to faster and more reliable solutions.

Sterilization technologies have been evolving from gamma towards ethylene oxide, then autoclave with increasingly higher temperatures. Peroxide plasma systems are increasingly popular as well. Modern materials must meet premium performance, biocompatibility and environmental regulatory expectations, and must maintain those characteristics after sterilization. The ability of any material to endure sterilization processing is a function of polymer type and grade, crystalinity, molded stresses (processing!), thickness (design!), and even packaging. Furthermore, each sterilization process itself includes variables that may affect material stability.

Radiation, for example, will involve a dosage range somewhere between the minimum necessary to achieve a sterility assurance level (SAL) and maximum acceptable dose for device and material function. Radiation source selection (e-beam, gamma or x-ray) will affect depth of penetration. Packaging is significant in radiation sterilization as well. Variations in type, orientation and bulk density will change the radiation dosage to various parts of the device(s) within the chamber. Just as radiation sterilizes by disrupting molecular bonds, polymers may be disrupted by undergoing either chain scission or cross linking. Either result can have undesirable effects such as embrittlement, softening and discoloration. Polyacetal, polypropylene, and PTFE are especially susceptible to radiation degradation. Certain materials can be compounded with stabilizers to minimize the effects of radiation (eg. PVC). Radiation techniques have a long history of effective sterilization of devices with intricate designs and inaccessible surfaces. Devices are ready for use immediately upon completion of the cycle, without chemical residues. The limitation is in the polymer response to the source, dose and other exposure variables.

Ethylene oxide (EO) sterilization is another older technology and has a generous window of material compatibility. However, there are a number of possible variables to consider during materials selection. EO conditions such as temperature, pressure changes, humidity, EO concentration and exposure time are optimized for device design through a validation process. Following sterilization, residual EO must be removed through a heated aeration process. This process is often the limiting factor in material selection.

Devices intended to be steam (autoclave) sterilized must consider temperature, humidity, pressure and potentially repeated cycling. Materials with low tolerance for heat and steam may soften, melt, discolor or react. Poorly bonded or sealed parts may provide an opportunity for steam to penetrate to conductors or other metal parts. Corrosion may be initially undetected, yet lead to costly failures in the field.

Peroxide systems must consider the effects of humidity and pressure cycling, and compatibility with the peroxide itself.

AAMI technical information report (TIR)17:2008 offers materials selection guidance for sterilization compatibility. The report describes key sterilization technologies including those listed above. Compatibilities of common materials are ranked on a general scale from poor to excellent. Since processing and design factors can lead to a considerable departure from the expected “material compatibility” the report offers some guidance for testing and qualification. These expectations should be discussed with knowledgeable design and materials engineers for optimum performance and sterilization compatibility.

Conclusion:

Biocompatibiltiy requirements are specific to each device type (surface, external communicating, implant) and contact duration (limited, prolonged, or permanent). Communicating those requirements to a knowledgeable supplier can optimize material selection and shorten the qualification process by avoiding over specifications or inadequate materials. Sterilization process compatibility must also be communicated early in the design process and validated under actual packaging and bulk-process conditions. NEWTC offers an extensive range of flexible materials with the full support of experienced design and materials engineers to help meet your regulatory and performance objectives.