



## ***The Use of Polyurethanes In Medical Device Applications***

Polyurethanes are commonly used in a number of medical device applications.

This brochure is designed to address many questions and issues relating to medical applications and to provide direction as to where further details may be obtained.

### ***1. What are the potential medical applications for polyurethanes?***

Polyurethanes have applications in catheter and general purpose tubing, hospital bedding, surgical drapes, wound dressings, as well as in a variety of injection molded devices. Their most common use is in short term implants. They are appropriate for a variety of uses where advantages such as cost effectiveness, longevity, toughness and high stress/strain properties are desired.

### ***2. What is the name of the organization that regulates medical device applications?***

The United States Food and Drug Administration's Center for Devices and Radiological Health (called "the Agency" or "FDA" in the remainder of this pamphlet) regulates medical devices.

### ***3. Are polyurethanes approved for medical device applications?***

Raw materials, including resins are not approved per se, by FDA. In fact, the great majority of medical devices entering the market today are never actually approved by FDA. Instead, manufacturers must notify the Center for Devices and Radiological Health (510(k) notification) of their own determination that their device is substantially equivalent to a type of medical device which has been on the market since 1976.

If the FDA agrees with the manufacturer's determination of substantial equivalence, marketing may commence. Therefore, the manufacturer's selection of a raw material or component part is based on its suitability for the intended use of the device, and its potential impact on a substantial equivalence determination. If substantial equivalence is not obtainable, then the device manufacturer must file a PMA (Pre Market Approval) on the new device.

Even the raw materials and component parts of devices which are subject to premarket approval are not approved individually. FDA will evaluate the safety and effectiveness of a device for its intended use, and approvals are granted to the final product based on these considerations.

After a PMA is granted, the substitution of one raw material, or one raw material supplier, will often require prior approval of a supplement to the PMA. Even in these cases, however, the material is not being approved per se; it is the material's suitability for use in a particular device that is being approved.

### ***4. Who is responsible for ensuring Medical Device compliance?***

It is the responsibility of the finished device manufacturer to make a determination of the suitability of all the component parts and raw materials to be used in the finished product.

### ***5. What influence does biocompatibility data supplied by material suppliers have on FDA acceptance and/or product liability concerns?***

FDA and device manufacturers are interested in the toxicological characteristics of the raw materials being considered for a device. The importance or desirability of certain toxicological characteristics will necessarily vary based on the intended use of the device.

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The use of a material to make an implant creates a need for more toxicology data than if the same material were used for an application that did not involve implantation. If the Agency needs more information on the toxicology of a raw material or component, it will ask the device manufacturer that is seeking approval to provide the information.

If a polyurethane supplier already has relevant toxicology data about its formulation, it can make that data available for review by the device manufacturer or through the FDA by establishing a Device Master File (MAF). The MAF is maintained as confidential by FDA, and will be reviewed only in conjunction with reviewing a product application that is submitted by a device manufacturer that has been authorized by the owner of the MAF (typically a resin supplier or formulator) to reference it.

## ***6. Is there anything beyond USP Class VI clearance that material suppliers can obtain? What does USP Class VI acceptance mean with respect to FDA clearance on a medical device?***

Establishing a USP Class VI rating has very little bearing on final compliance with FDA regulations; it merely states that the product exhibits a very low level of toxicity under the conditions of testing. Historically, this classification had been a standard in the industry to have a resin considered viable as a product for medical device applications. Beyond

USP Class VI testing, other standard test methods that are generally accepted are cytotoxicity, hemolysis and physio-chemical. FDA also has adopted International Standards Organization (ISO) standard 10993—"Biological Evaluation of Medical Devices Part I—Evaluation and Testing" which for some medical device manufacturers has replaced USP Class VI as the standard to have a resin considered viable as a product for medical devices.

## ***7. What is the definition of "implant" and what are its consequences for a device categorized as an implant?***

"Implant" is defined as a device that is placed into a surgically or naturally formed cavity of the human body and is intended to remain implanted continuously for a period of thirty days or more.

The Agency may also use its discretion to determine that devices placed in the body for shorter periods of time are implants [21 C.F.R. part 860.3(d)]. Implants undergo more thorough review by FDA than most devices that are not implants.

A device that is placed into a surgically or naturally formed cavity of the human body, but which is intended to remain in place continuously for less than 30 days, is not considered to be an "implant" for regulatory purposes, unless the Commissioner determines otherwise to protect human health. Such devices are often referred to informally as "short term implants."

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