Technical Bulletin

USP Class VI and BISCO® MS Silicone Compliance
for Medical and Life Science Applications

Material selection for medical and life science applications is critical to ensure quality, performance, and safety. One standard that plays an important role is USP Class VI.

What is USP Class VI?

USP Class VI is a standard set by the United States Pharmacopoeia (USP) that focuses on the biological reactivity of plastics in vivo used for medical devices.

Specifically, the testing evaluates a material's response when it comes in contact with living tissue to check for any harmful effects.

USP Class VI, while the most stringent of the six USP tests, is considered significantly less stringent than ISO 10993.

USP Class VI may be sufficient for most Class I medical devices while ISO 10993 is required for permanently or semi-permanently implanted medical devices.

Why is USP Class VI important?

Adherence to USP Class VI indicates clear commitment to upholding the most stringent standards of bio-compatibility and safety.

Using a USP Class VI material contributes to improving medical device safety and quality by assuring:

- Biological Safety
- Compliance with Regulatory Requirements
- Minimization of Risk
- Quality of Material and Performance

What applications is USP Class VI related to?

USP Class VI can be applicable to:

- Dental Products
- Seals and Gaskets
- Surgical Instruments
- Catheters and Tubing
- Drug Delivery Systems
- Laboratory Consumables
- Bioprocessing Equipment

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More Information on USP Class VI

USP Class VI involves three in-vivo biological reactivity evaluations:

EVALUATIONS	PURPOSE
Acute Systemic Toxicity (Systemic Injection) Test	Measures toxicity and irritation when a sample of the compound is administered orally, applied to the skin, and inhaled
Intracutaneous Test	Measures toxicity and localized irritation when the sample is in contact with live subdermal tissue (specifically, the tissue that the medical device is intended to contact)
Implantation Test	Measures toxicity, infection, and irritation of an intramuscular implantation of the compound into a test animal over several days

USP CLASSIFICATION OF PLASTICS I-VI

TEST	EXTRACTS	SQN AJ?QQ					
USP Class		I	II	III	IV	V	VI
Systemic Injection Test-injection in test model 1	Sodium Chloride (intravenous)	X	X	X	X	X	X
	Alcohol Saline (intravenous)		X	X	X	X	X
	Polyethylene Glycol (intraperitoneal)			X		X	X
	Vegetable Oil (intraperitoneal)			X	X	X	X
Intracutaneous Test-injection in test model 2	Sodium Chloride (intravenous)	X	X	X	X	X	X
	Alcohol Saline (intravenous)		X	X	X	X	X
	Polyethylene Glycol (intraperitoneal)					X	X
	Vegetable Oil (intraperitoneal)				X	X	X
ImplantationTest-strips implanted in test model 2	None				X		X

Learn More

Contact a Rogers Sales Engineer for more Medical and Life Science application support, or visit the BISCO MS SILICONES PRODUCT PAGE.

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