



PRODUCT DATA

Medical Grade Compounds

Precision Associates manufactures a number of compounds that are suitable for use in medical applications requiring body or body fluid contact. These materials have been tested by independent laboratories and/or our material suppliers to assess their ability to meet requirements as defined by several standards organizations. The definitions of our medical grades are listed below. PAI compounds that meet these requirements are outlined on the back of this document.

USP VI / ISO 10993 Grade

The United States Pharmacopeia (USP) is an official public standards setting authority for medicines and other health care products manufactured or sold in the United States. PAI rubber compounds have been tested to meet USP <87> and <88> Biological Reactivity Tests for Class VI materials and USP <661> Physicochemical Tests for plastics. ISO 10993 is a 20 part series of biological evaluations used to confirm suitability in Medical Devices (see below). Additionally, PAI USP VI / ISO 10993 compounds are formulated with materials sanctioned under the FDA Code of Federal Regulations, Title 21, Part 177.2600. Each lot undergoes physical property testing.

Precision Associates recommends the use of the above materials in medical devices requiring contact with pharmaceuticals, human or animal bodies and body fluids. Although tested for short term implantation, we do not recommend their use for implantation without further testing.

Biomedical Grade

In addition to meeting all of the requirements of the USP VI Grade materials, Biomedical Grade silicone elastomers undergo additional biocompatibility testing including 90 day implantation. Each lot is screen strained to remove particulate contamination, and is subjected to a tissue culture testing.

Biomedical grades are suitable for use in the same applications as USP VI materials and for short term implantation (up to 29 days).

Implantable Grade

Silicone grades suitable for long term implantation are also available. Each application must be approved by Precision Associates and the material manufacturer prior to purchase. Please contact PAI for additional information on Implantable Silicone Grades.



ISO 10993 is a series of standards for evaluating the effects of medical devices and their component materials on the body. Those commonly requested for rubber products are -5 (vitro cytotoxicity), -10 (irritation and skin sensitization), -11 (systemic toxicity).

Precision Associates' medical grade products are produced and packaged in our ISO 14644-1 Class 7 certified clean room. Although manufacture takes place in a clean room, it is not a sterile environment. Precision Associates medical grade materials may be sterilized by EtO, autoclave or gamma radiation.

Precision Associates does not guarantee fitness for use or any application. Purchaser is responsible for determining suitability of function. Certification is supplied with each shipment.



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USP VI / ISO 10993 Materials

| | EPDM | | Fluoroelastomer | | | FKKM |
|-----------|--------|--------|-----------------|-------|-------|--------|
| Durometer | Black | White | Orange | White | Black | White |
| 70 | 423767 | 423725 | 48751 | 48725 | 48767 | 434725 |

| | Bromobutyl | | Polyisoprene | | Urethane | |
|-----------|------------|--|--------------|--|----------|--|
| Durometer | Cream | | Cream | | Clear | |
| 40 | | | 41424* | | | |
| 50 | 413524* | | 41524* | | 435524 | |
| 75 | | | | | 435724 | |

Dow Corning Platinum Cured Silicone Compounds[∞]

| Durometer | Base Material | Clear | White [†] | Black [†] | Red [†] | Blue [†] | Green [†] | Yellow [†] |
|-----------|---------------|-------|--------------------|--------------------|------------------|-------------------|--------------------|---------------------|
| 15 | MED-4014 | 49124 | * | * | * | * | * | * |
| 50 | C6-135 | 49526 | 49525 | 49529 | 49559 | 49562 | 49523 | 49556 |
| 60 | C6-150 | 49626 | 49625 | 49629 | 49659 | 49662 | 49623 | 49656 |
| 70 | C6-165 | 49726 | 49725 | 49729 | 49759 | 49762 | 49723 | 49756 |
| 80 | C6-180 | 49826 | 49825 | 49829 | 49859 | 49862 | 49823 | 49856 |

Biomedical Grade Materials[∞]

Dow Corning Q7 Platinum Cured Silicone Compounds

| Durometer | Base Material | Clear | Red [†] | Black [†] | Blue [†] |
|-----------|---------------|-------|------------------|--------------------|-------------------|
| 40 | Q7-4735 | 49470 | 49449 | * | * |
| 55 | Q7-4750 | 49670 | 49549 | * | * |
| 75 | Q7-4765 | 49770 | 49749 | 49767 | * |
| 80 | Q7-4780 | 49870 | 49849 | * | * |

♦ Tested to meet ISO 10993-5. USP testing pending.

∞ Tested to meet ISO 10993-3/4/5/6/10/11

* Contact Precision Associates for information on this formulation.

† Colored silicone compounds use applicable grade polymer and colorants tested to meet USP VI and ISO 10993.



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