



## Medical Seal Solutions **YOUR WAY!**

Precision Associates specializes in close tolerance, custom molded precision rubber components and standard seals for medical, dental, and pharmaceutical industries.

Items intended for medical use are produced in our 6,000 sq. ft. ISO 14644-1 Class 7 (10,000) Clean room complete with HEPA filtration, atmospheric pressure, air-flow, temperature, and humidity monitoring systems. Specially treated water used to wash parts prior to packaging is tested for electrical resistivity to ensure purity and prevent the introduction of pyrogens (fever inducing bacteria) during the cleaning process.

All stages of rubber production from mixing of the compound through packaging are performed within the Clean Room facility, including, cryogenic and mechanical de-flashing. Segregated equipment and work rooms are maintained for silicone and non-silicone mixing and secondary operations.



PAI manufactures a number of compounds that are suitable for use in medical applications requiring body or bodily fluid contact. Many materials meet FDA, USP Class VI and ISO 10993 requirements. Biomedical grade silicone elastomers undergo additional biocompatibility testing and are suitable for short term implantation up to 29 days. Silicone grades suitable for long term implantation are also available. Each application requires prior approval from Precision Associates and the material manufacturer. PAI can develop a proprietary compound to function in specific operating parameters if an existing material cannot meet the requirements.

|            | Silicone | EPDM | Viton®<br>(FKM) | FFKM | HNBR | NBR |
|------------|----------|------|-----------------|------|------|-----|
| FDA        | X        | X    | X               | X    | X    | X   |
| USP VI     | X        | X    | X               | X    |      |     |
| ISO 10993  | X        | X    | X               |      |      |     |
| Biomedical | X        |      |                 |      |      |     |



With over 2,500 O-Ring sizes and many other catalog seals, we can provide parts from existing tools out of medical grade compounds. For special items, our in-house tooling facility can readily make a mold to meet customer specifications.

As with all products manufactured by PAI, 100% visual inspection is automatically included. Applicable certifications are provided with each shipment and all material and process traceability is maintained indefinitely.



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Precision Associates currently provides products in these applications:



- ◆ Gas Handling
- ◆ Electronic Monitoring
- ◆ Blood Handling
- ◆ Vaccine/Medicine Delivery
- ◆ Surgical Instruments

- ◆ Hearing Aids
- ◆ Laser Devices
- ◆ Drainage Systems
- ◆ Laboratory Equipment
- ◆ Medical Electronics



- ◆ Dialysis/Renal Care
- ◆ Urologic/Gynecologic Equipment
- ◆ Ophthalmic Lens Production
- ◆ Endoscopy
- ◆ CTO Recanalization

- ◆ Dental Instruments
- ◆ Dental Implants
- ◆ Veterinary Equipment
- ◆ Pharmaceutical
- ◆ Biotech
- ◆ Prosthetics

