

Assembly and Fabrication of Silicone Medical Devices



Our Capabilities:

Parker's Composite Sealing Systems Division (CSS) manufactures various single-use, as well as short & long-term implantable silicone medical devices for cardiovascular, nutritional, orthopedic, respiratory, urological and other general surgery OEMs. Our engineering and quality assurance teams work in close conjunction with OEM medical device engineers to optimize manufacturability, quality, cost-effectiveness and overall product-to-market timeline of newly designed components and devices.

Parker's Composite Sealing Systems Division also offers medical device OEMs product with packaging and outsourced product sterilization services.



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- All silicone medical devices are manufactured with silicone materials from Dow Corning, Momentive, NuSil, Shin-Etsu and Wacker that will pass ISO 10993 tests.
- All silicone medical devices are manufactured in ISO Class 7 and ISO Class 8 Cleanrooms in FDA registered facilities.
- All silicone devices can be sterilized with autoclave, ethylene oxide or gamma radiation.



ENGINEERING YOUR SUCCESS.



Silicone Dual-Port Catheter



Silicone Wire-Reinforced Tracheostomy Tubes



Silicone Peritoneal Dialysis Catheter

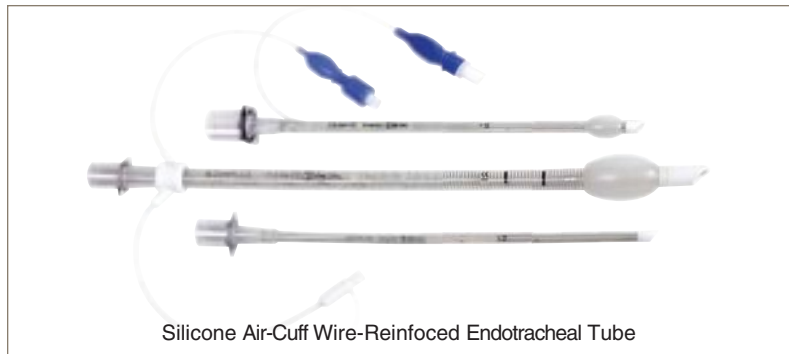


Silicone Air-Cuff Wire-Reinforced Tracheostomy Tube with Adjustable Neck Flange

Our Capabilities (cont'd)

With in-house mold design and mold building capabilities, Parker's Composite Sealing Systems Division can provide rapid prototypes of new components or devices so that OEM engineers can conduct functional field tests during the ongoing development of a device or component.

Parker's Composite Sealing Systems Division manufactures single-use as well as short & long-term implantable silicone medical devices in an ISO 13485, FDA registered facility with ISO Class 7 and ISO Class 8 Cleanrooms.



Silicone Air-Cuff Wire-Reinforced Endotracheal Tube

Medical Markets Served:

- Cardiovascular
- Anesthesiology
- Bariatric surgery
- Endoscopy
- Nutritional
- Ophthalmology
- Orthopedics
- Reconstructive surgery
- Urology
- General surgery
- Wound Management

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- The user, through its own analysis and testing, is solely responsible for making the final selection of the system and components and assuring that all performance, endurance, maintenance, safety and warning requirements of the application are met. The user must analyze all aspects of the application, follow applicable industry standards, and follow the information concerning the product in the current product catalog and in any other materials provided from Parker or its subsidiaries or authorized distributors.

-To the extent that Parker or its subsidiaries or authorized distributors provide component or system options based upon data or specifications provided by the user, the user is responsible for determining that such data and specifications are suitable and sufficient for all applications and reasonably foreseeable uses of the components or systems.

