

# Assembly & Fabrication of Silicone Medical Devices

USP Class VI Biocompatible materials



## Custom Silicone Medical Devices

Parker Medical Systems Division 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 Medical Systems Division also offers medical device OEMs product with packaging and outsourced product sterilization services.

(continued, see reverse side)



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## Product Benefits:

- All silicone medical devices are manufactured with silicone materials from Dow Corning, GE, NuSil, Shinetsu, and Wacker that will pass USP Class VI (ISO 10993) tests.
- All silicone medical devices are manufactured in ISO Class 8 (Class 100,000) and ISO Class 7 (Class 10,000) Cleanrooms in FDA Registered facilities.
- All silicone devices can be sterilized with autoclave, ethylene oxide, or gamma radiation.

## Medical Markets served:

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



ENGINEERING YOUR SUCCESS.

## Custom Silicone Medical Devices (Continued)

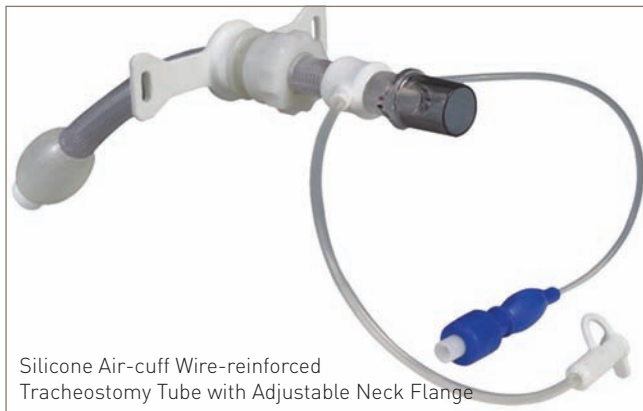
With in-house mold design and mold building capabilities, Parker Medical System Division can provide rapid prototypes of new components or devices so that OEM engineers can conduct functional field tests during the ongoing development of a device or component.

Parker Medical System Division manufactures single-use as well as short & long-term implantable silicone medical devices in an ISO 13485, FDA Registered facility with ISO Class 8 (Class 100,000) and ISO Class 7 (Class 10,000) Cleanrooms.

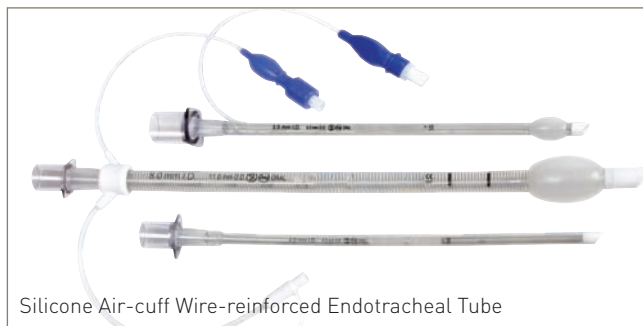
Please contact us with your Medical device Assembly & Fabrication requirements.



Silicone Wire-reinforced Tracheostomy Tubes



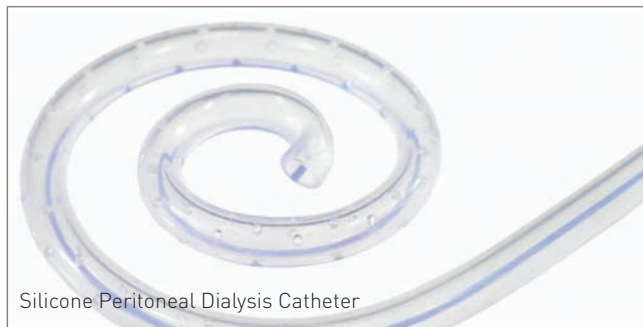
Silicone Air-cuff Wire-reinforced Tracheostomy Tube with Adjustable Neck Flange



Silicone Air-cuff Wire-reinforced Endotracheal Tube



Silicone Dual-port catheter



Silicone Peritoneal Dialysis Catheter

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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.

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