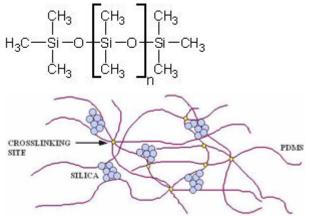
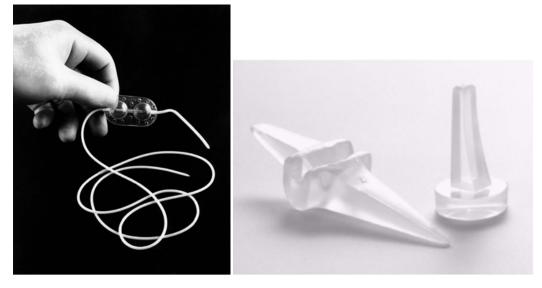
## BOTM: March 2010

## Silicone Elastomer

Silicones are a general category of synthetic polymers whose backbone is made of repeating silicon-tooxygen bonds. In addition to their links to oxygen to form the polymeric chain, the silicon atoms are also bonded to organic groups, typically methyl. Accordingly, the most prevalent form of silicone polymer is polydimethylsiloxane, abbreviated PDMS. Silicone polymers can form three-dimensional networks through the formation of bonds between adjacent chains, a process known as "cross-linking." In addition to cross-linked silicone polymer, most silicone elastomers also incorporate "filler," which extends and reinforces the matrix, providing increased strength and hardness. While industrial silicones might incorporate various filler materials, elastomers for health care applications generally use filler comprised of fumed (amorphous) silica, which is often chemically treated with silanes to enhance integration in the matrix, resulting in improved strength and tear resistance.



Silicone elastomers can be processed into device components by extrusion, molding, coating and calendaring. They are chemically resistant, stable over a wide temperature range, easily sterilized, biocompatible and very durable. Since first used in 1946 for bile duct repair, silicone elastomers have become a mainstay biomaterial for long- and short-term implants as well as extracorporeal tubing and other medical devices. Silicone elastomer, or silicone rubber as it is sometimes known, finds application in virtually every part of the human body, literally from head to toe and from hand to heart.





In the 1990s, silicone elastomer-shelled breast implants became the subject of allegations regarding safety. Although silicone elastomers remained available for health care applications, litigation concerns caused some silicone suppliers to limit the implant applications they would support. Extensive and unprecedented epidemiology and other safety testing conducted to address these concerns support silicone implant safety. Today, silicone elastomers are one of the most thoroughly tested and important synthetic biomaterials.

More information regarding silicone biomaterials can be read in Biomaterials Science: An Introduction to Materials in Medicine, Ratner et al., ed.

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