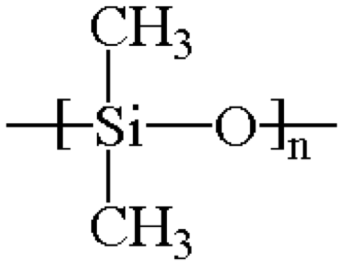
Silicones



The polymer can be synthesised in various forms, from gelatinous to rubberised.

One of the least attractive properties of conventional silicone elastomers in device manufacturing is that the materials require covalent cross-linking to develop useful properties.

Linear or branched silicone (polydimethylsiloxane (PSX)) homopolymers are viscous liquids or millable gums at room temperature.

Silicone elastomers have remarkably low glass-transition temperatures and maintain their flexibility over a wide temperature range, enabling them to withstand conditions from cold storage to steam autoclaving. They have high permeability to gases and many drugs, advantageous respectively in wound care or in transdermal drug delivery. They have low surface tension and remarkable chemical stability, enabling biocompatibility and biodurability in many long-term implant applications.

However, versatile as they are, present-day silicone materials still have limitations. The **mechanical properties** of silicone elastomers, such as tensile strength or tear resistance, are somewhat lower than for other implantable elastomers such as polyurethanes (although generally speaking, polyurethanes are less biodurable). While resistant to a wide array of chemical environments, silicone elastomers are susceptible to **degradation** in very strongly basic or acidic conditions, such as those found in the stomach. Like all **hydrophobic** implant materials, **silicones are quickly coated with proteins when placed in tissue contact; and a scar tissue capsule forms to surround an implant during wound healing, walling it off from the host.** Additionally, silicone elastomers are thermosetting materials, requiring different processing from conventional thermoplastics, which can on occasion be seen as a drawback.

Silicone as a biomaterial

Silicone has unique material properties that make it ideal for certain applications in the biomedical field. Its hydrophobic nature, low surface tension, and chemical and thermal stability lend to biodurability and generally favourable biocompatibility.

While biocompatibility remains a controversial term, the following working definition is often applied to biomedical applications of silicones - **a material's ability to elicit an appropriate response in a specific application.**

The breast implant controversy

Historically, the most controversial silicone device is the synthetic silicone gelatinous breast. **Silicone breast implants are semi-cross linked, allowing for some structural stability, but also flexibility.** First created and implanted in 1962, this device was considered far superior to the already existing breast foam implant technology.

In the early 1990s, after approximately 30 years of success, the cosmetic surgery community and breast implant manufacturers received criticism. Claims of illness caused by the devices ranged from pain and suffering as a result of capsular rupture to autoimmune disease.

In 1992, under pressure from numerous entities, the FDA restricted sales of silicone breast implants, despite the lack of credible evidence to conclude that the product was not safe and effective. In general, there was concern that the implants would rupture and silicone would travel to other vital bodily systems.

In 1995, Dow Corning Company, the world's leading silicone manufacturer at the time, filed for Chapter 11 bankruptcy as a result of facing 20,000 lawsuits and about 410,000 potential breast implant-related claims. In 1999, a settlement was reached to compensate patients and healthcare companies in excess of $4 billion.

Interestingly, researchers studying the safety and efficacy of silicone breast implants found some medical complications, but proved no causal link between the product and the incidence of breast cancer or connective tissue autoimmune reactions in women with silicone implants. **In 2006, the FDA lifted the ban on silicone breast implants and manufacturers modified their practices to produce improved silicone products.**

All breast implants are constructed with a smoothed or textured shell of silicone elastomer. **The majority of implants are filled with saline rather than silicone gel, after the 1992 FDA voluntary moratorium on silicone gel implants; however, gel-filled implants are making a comeback owing to more lifelike mechanical properties**.

Fibrous capsular contraction is the most common complication in breast surgery, with long- term contracture incidence reported at 15–25%.

As with any foreign object implanted in the body, the host response to a breast implant is to construct a fibrous capsule around the foreign-body, "walling off" the implant from the rest of the body. During the first several months post-implantation the fibrous capsule begins to contract, resulting in breast firmness that may lead to patient discomfort and disfigurement.

Several possible factors contribute to breast implant capsular contracture, including implant surface (smooth versus porous), implant placement (submuscular versus subglandular), implant shape (i.e., fill volume), bacterial infection, bleeding, surgical technique, post-operative care (i.e., breast massage), and patient.

TEXTURE: The collagen arrangement hypothesis is that irregularly arranged collagen fibers at **textured surfaces** are less able to generate cooperative contractile forces typical of maturing scar tissue, while another hypothesis is that irregularly aligned collagen fibers are more susceptible to collagenase degradation. Textured implants have been shown to have more macrophages and less collagen surrounding them compared to smooth implants, indicating that macrophages may be degrading the capsule as it forms, minimizing capsule thickness.

- The product is water-resistant. It cannot be easily warmed up or cooled down, and it does not allow electricity to pass through it. So the polymer's fails to blend in to its new biological environment, and so the body must change to suit it.

- Knowing how important it is for the body to maintain its controlled environment, silicone's very properties seem to imply that it is biologically incompatible.

- The most common complications caused by the silicone breast implant are calcification of the capsule making the breasts painful and hard, and implant rupture.
- Implant rupture rates is about
  - 30% at five years,
  - 50% at 10 years,
  - 70% at 17 years post implantation

Poly Implant Prothèse (**PIP**) was a French company founded in 1991 that produced silicone gel breast implants. The company was preemptively liquidated in 2010 following the revelation that they had been illegally manufacturing and selling breast implants made from **cheaper industrial-grade silicone since 2001** (instead of the mandated medical-grade silicone they had previously used). The **hundreds of thousands** of unapproved implants sold globally by PIP from 2001 to 2010 were found to have a 500% higher risk of **rupturing or leaking** than approved models, as well as being implicated in at several deaths due to systemic toxicity and several cases of induced **breast cancer**. The scandal, which produced fears of a massive health disaster, prompted a full recall of the company's implants by the French health ministry in 2010, by which time the company was already defunct

PIP was founded in 1991by the Frenchma Jean-Claude Mas, born in 1939, a former butcher and later medical sales representative for the Bristol Myers company for 15 years. Mas had previously teamed up with plastic surgeon Henri Arion, who had introduced breast implants to France in 1965. After Arion died in a plane crash, Mas went on alone and launched PIP in 1991

Starting in 1991, the company produced approximately 2 million sets of silicone breast implants over a 20-year period. The implants were exported to Latin American countries such as Brazil,[2] Venezuela[7] and Argentina, Western European markets including Britain (25,000), Germany, Spain and Italy, as well as Australia (8900).

Following the FDA ruling in 2000 which banned silicone breast implants in the US market (leading to a slump in sales worldwide), Mas sought to "tighten PIP's belt" and recoup some of its lost market share by severely cutting costs. In particular, Mas was credited with the idea that by switching PIP's silicone from externally purchased medical-grade to in-house produced industrial-grade, huge savings (on the order of 90%) could be generated that would ensure profits remained high no matter the market. **As one PIP engineer later noted, this decision involved a relatively small change in the formula for the silicone, enough so that only superficial differences in the end product were noted. However, none of the relevant regulations were followed for manufacturing medical implants, and no pre-launch tests were conducted.**