

Silicone Breast Implants

The applications of silicone, whether used as an oil, gel or solid, are equally extensive in the medical field. Here we provide answers to some of your questions about silicones, more specifically breast implants, and to provide an overview of silicones.

What is silicone?

The purpose of this document is to provide answers to some of your questions about silicones, more specifically breast implants, and to provide an overview of silicones, their common uses, and why the medical profession chooses to use them. The reference numbers throughout the text indicate the sources of the information discussed in this page. Please refer to the “References” section for more information.

As with any medical device or drug, the risk of possible adverse effects must always be weighed against the ability to provide benefits. If you have any questions, please be sure to ask your physician.

Please note that this document is not intended to supplement or replace product labeling or medical advice regarding the risks and benefits associated with implantable devices.

Silicones are a family of chemical compounds. They are made from silicon, a naturally occurring element found in sand, quartz, and rock. After oxygen, silicon is the most common element in the earth’s crust, and becomes silicone when it is combined with oxygen, carbon, and hydrogen.

Depending on the arrangement of the molecules, silicones can be manufactured in a variety of forms, including oils, gels and solids.

Consumer and medical products

Silicones have been a part of the consumer industry for over 50 years. Because they can be manufactured in various ways, silicones appear in a wide variety of products that most of us use every day. Hairsprays, suntan lotions and moisturising creams are just some of the consumer products that contain one form of silicone called dimethicone.

The applications of silicone, whether used as an oil, gel or solid, are equally extensive in the medical field. For example, the lubricating qualities of silicones make them ideal for coating surgical needles and suture thread, as well as the interior surfaces of syringes and bottles used for the storage of blood and intravenous medicines. Protective silicone coatings have also been used in pacemakers and heart valves.

Other medical devices utilising silicones include: artificial joints, catheters, drainage systems, facial implants, tissue expanders, and breast implants. Silicone products have been shown to be biocompatible (i.e. accepted by the human body without adverse reaction), reliable, flexible, and easy to sterilise, making them an ideal choice for both implantable and non-implantable medical devices.

“I received a booklet from the hospital containing information about silicone. The different uses were mentioned in this booklet as well. I was really surprised to find out that things used on a daily basis such as lipstick and mineral water contain silicone as well. Nobody seems to be bothered by this. It made me therefore very angry that so much negative publicity appears in the media about silicone breast implants.”



Mr Lucian Ion FRCS(Plast)
*Consultant Plastic Aesthetic and
Reconstructive Surgeon*

Safety issues

Safety issues concerning the use of silicone in medical devices have primarily focused on the possible link between breast implants (both saline-filled and gel-filled) and certain diseases, including breast cancer, and connective tissue disorders (also known as autoimmune diseases) such as lupus, scleroderma, and rheumatoid arthritis.

Silicone materials have been extensively tested in laboratory studies, as well as clinical studies (which study human health). Much scientific evidence has already been gathered on the basis of the one to two million women who have received breast implants. The following is a summary of current published scientific information concerning silicone breast implants, breast cancer, and connective tissue disorders (CTDs).

Breast cancer

Breast cancer occurs in tissues rich in ducts and glands, and may spread throughout the body. About one in every ten women develops breast cancer in her lifetime. Because of the safety issues surrounding silicone in medical devices and the incidence rate of breast cancer in the human population, questions have been raised concerning increased risks of developing breast cancer for women with breast implants.

As the following clinical studies demonstrate, the likelihood of developing breast cancer does not appear to increase following the use of silicone breast implants.

- A 1986 University of Southern California study published in *Plastic and Reconstructive Surgery* investigated over 3,000 women in the Los Angeles area who received silicone breast implants between 1959 and 1980. The results showed no increased risk of breast cancer following breast implant surgery compared with standard incidence rates.
- A 1997 fourteen-year update of this study monitored the same group and confirmed the original findings.
- A 1992 University of Calgary study published in the *New England Journal of Medicine* investigated over 11,000 women in Alberta, Canada, who received silicone breast-implants between 1973 and 1986. This study “did not find an increased risk of cancer among women who had * received breast implants, although the length of follow-up, the completeness of follow-up, and the size of the cohort would have allowed the detection of such a risk”.
- A 1996 Georgia, New Jersey, and Washington study published in *Plastic and Reconstructive Surgery* investigated over 2,000 women with breast implants. The results of this study are consistent with those of the Los Angeles and Alberta studies, finding no association between silicone breast implants and breast cancer.

Silicone breast implants and breast cancer detection

Most studies using standard mammography have shown no difference in the average time required to detect breast cancer between women with and without breast implants, nor have they shown a difference in the stage of disease detected.

However, because implants may interfere with standard mammography by obscuring some underlying tissue and/or by compressing overlying tissue, you should inform your radiologist about your implants and request diagnostic mammography. In particular, your radiologist should be experienced in current mammographic displacement techniques (such as the Eklund technique) for imaging the breast tissue around the implants and should provide you with multiple mammographic images. Diagnostic mammography may facilitate early diagnosis of small masses that can be difficult to see with standard mammography.

129 Harley Street, London, W1G 6BA

Telephone: 020 7486 7757 · Fax: 020 7224 5011

www.aesthetic-plastic-surgery.co.uk



Mr Lucian Ion FRCS(Plast)
*Consultant Plastic Aesthetic and
Reconstructive Surgeon*

“I think that the commotion in the states can be summed up as a lot of scare mongering among women. It is always the same: every time some negative news appears in the media, women come to my office and want to be reassured about the safety of silicone. Obviously, women would like to have answers to all their questions and I provide them with these answers. I think that this situation will never change as silicone implants are an interesting and for many people sensational topic. Because of this negative publicity it is hard for women to get breast enlargement accepted by society. Silicone is a safe material that is used for many medical applications. I do not see any reason to stop implanting silicone breast implants as long as there is no scientific evidence to suggest that these implants cause illness.”

Silicone breast implants and connective tissue disorders

Connective tissue disorders (CTDs) are described as a group of generalised disorders affecting the connective tissues (i.e. fat, bone, and mucous membrane). The theory has been presented that silicone breast implants may increase the risk of developing a CTD. As the following clinical studies indicate, actual statistical information has provided no significant evidence that silicone breast implants greatly increase the risk of developing a CTD.

- A 1993 University of Texas, Houston study published in the *Annals of Plastic Surgery* investigated 603 women undergoing reconstructive breast surgery between 1986 and 1992. In this study 250 women underwent breast reconstruction with silicone gelfilled breast implants and 353 women underwent breast reconstruction utilising their own tissue. The results of this preliminary report found that “the incidence of autoimmune diseases in mastectomy patients receiving silicone gel implants is not different than in patients who had reconstruction with autogenous [patient’s own] tissue”.
- A 1994 Mayo Clinic study published in the *New England Journal of Medicine* compared 749 women who had breast implant surgery between 1964 and 1991 with 1,498 women who did not have breast implant surgery. The results of the study showed “no association between breast implants and the connective tissue diseases and other disorders that were studied”.
- A 1995 Harvard/ Brigham’s Hospital study published in the *New England Journal of Medicine* analysed 14 years of follow-up data from the Nurses Health Study Cohort. This involved a survey of over 87,000 women, with and without breast implants. The results showed no “association between silicone breast implants and connective tissue diseases”.
- Doctors at the Karolinska Institute in Stockholm, Sweden studied more than 7,000 women who had had breast implants and compared them with a group of more than 3,000 who had undergone breast reduction surgery. They found no meaningful association between women with implants and cases of connective tissue, or immunological, disease. In fact the women with augmented breasts were statistically slightly less likely to have encountered these diseases than the breast reduction group.
- A statement prepared and published by the American College of Rheumatology (ACR) - a task force of plastic surgeons, rheumatology specialists, and the American Medical Association - advises that while there may be a theoretical risk of CTDs, especially for a patient who already has a CTD, there is “no reason to discourage women from considering breast [implant surgery] on the basis of acquiring or exacerbating a connective tissue disorder”.

129 Harley Street, London, W1G 6BA

Telephone: 020 7486 7757 · Fax: 020 7224 5011

www.aesthetic-plastic-surgery.co.uk



Mr Lucian Ion FRCS(Plast)
*Consultant Plastic Aesthetic and
Reconstructive Surgeon*

“I could discuss everything with my surgeon including complications and illnesses. I was a little worried about capsule formation (scar tissue). I had understood that this could happen if the body decided to reject the implant. I was relieved when the surgeon explained that this is a normal bodily reaction. It also happens when you get a splinter in your finger. The capsule does not cause any suffering as long as it does not contract. Prior to my surgery, I was also a little scared of all the illnesses which were said to be a consequence of having silicone breast implants. Following surgery, there is nothing wrong with my health and I no longer feel any fear. The reason for this is that to date, no scientific evidence has been found to show a connection between silicone breast implants and their so-called connected illnesses.”

Testing for silicone in the body

Researchers have recently developed tests for detecting silicone in the body. These tests have become a factor with regard to the safety issues of silicone breast implants and the human body's response to the silicone found in these products.

As yet neither the FDA (Food and Drug Administration) nor the European Ministries of Health have approved any of these detection tests, and they have indicated that the results of these tests should be treated with caution. Furthermore, the regulatory authorities have indicated that “determining ... silicone is present in the body fluids does not indicate whether a person is sensitive to these substances or at risk for any specific disease ... [and] the significance [of silicone detection] would be unclear.”

Conclusion and references

A number of clinical studies have shown that there is no conclusive scientific evidence that silicone materials in breast implants greatly increase the risk of developing breast cancer or CTDs.

We hope this document has given you a better understanding of the issues surrounding silicones, especially silicone breast implants. If you have any further questions about silicones and breast implants, please ask your physician for more information.

References

- LeVier RR, Harrison MC, Cook RR, Lane THG. What is silicone? *Plastic and Reconstructive Surgery*. 1993; 92 (1): 163-167.
- Deapon DM, Brody GS, et al. The relationship between breast cancer and augmentation mammoplasty: an epidemiologic study. *Plastic and Reconstructive Surgery*. 1986; 77(3): 361-367.
- Deapon DM, Bernstein L, Brody GS. Are breast implants anticarcinogenic? A 14-year follow-up of the Los Angeles Study. *Plastic and Reconstructive Surgery*. 1994; 99 (5): 1346-1353.
- Berkel H, Birdsell DC, et al. Breast Augmentation: A risk factor for breast cancer? *New England Journal of Medicine*. 1992; 326 (25): 1649-1653.
- Brinton LA, Malone KE, et al. Breast enlargement and reduction: Results from a breast cancer case-control study. *Plastic and Reconstructive Surgery*. 1996; 97(2): 269-275.
- Shusterman MA, Kroll SS, et al. Incidence of autoimmune disease in patients after breast reconstruction with silicone gel implants versus autogenous tissue: a preliminary report. *Annals of Plastic Surgery*. 1993; 3 I (1): 1-6.
- Gabriel SE, O'Fallon WM, et al. Risk of connective-tissue diseases and other disorders after breast implantation. *New England Journal of Medicine*. 1994;330(24): 1697-1702.
- Sanchez-Guerro J, et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *New England Journal of Medicine*. 1995; 332 (25): 1666-1670.

129 Harley Street, London, W1G 6BA

Telephone: 020 7486 7757 · Fax: 020 7224 5011

www.aesthetic-plastic-surgery.co.uk



Mr Lucian Ion FRCS(Plast)
*Consultant Plastic Aesthetic and
Reconstructive Surgeon*

- Nyren O, Yin L, Josefssons S, et al. Risk of connective tissue disease and related disorders among women with breast implants: a nation-wide retrospective cohort study in Sweden. *British Medical Journal*. 1998; 3 16: 417-422.
- Brody GS, Deapen DM, et al. Consensus statement on the relationship of breast implants to connective-tissue disorders. *Plastic and Reconstructive Surgery*. 1996; 90(6): 1102-1105.
- US Food and Drug Administration. Breast Implant Information Package. March 1996.

Further Reading on Breast Augmentation:

Independent Review Group on Silicon Breast Implants:
Breast Augmentation
www.silicone-review.gov.uk

Medical Devices Agency:
Breast Augmentation at
www.medical-devices.gov.uk

Department of Health- Information for women considering
breast implants:
Breast Augmentation at
www.doh.gov.uk/bimplant

Our services

From your first visit to Aesthetic Plastic Surgery's handsome Harley Street offices, you'll work directly with Consultant Plastic, Aesthetic and Reconstructive Surgeon Mr. Lucian Ion, the practice's director.

Together, you'll explore the possibilities and discuss the results you can expect.

Imaging software will be used to show you how you might look after your procedure and every aspect of your treatment, from evaluation through surgery to post surgical care, will be carefully explained.

More Information

Naturally, there will be many questions you will want to ask before making any decisions about undergoing surgery. Also you will wish to meet your Surgeon - having trust and confidence in one's Surgeon is very important.

Surgery is unique to every patient and a detailed discussion and assessment between you and your Consulting Surgeon is essential in enabling you to make a decision based on correct personal information and advice.

Arranging a medical consultation does not obligate you to anything other than attending the appointment. There is no obligation to proceed with treatment. This is entirely a matter for your decision, after the surgeon has decided on the feasibility and accepted you as suitable.

If you would like to know more information we will be happy to answer any queries either by email, letter or telephone, so please do not hesitate to get in touch.