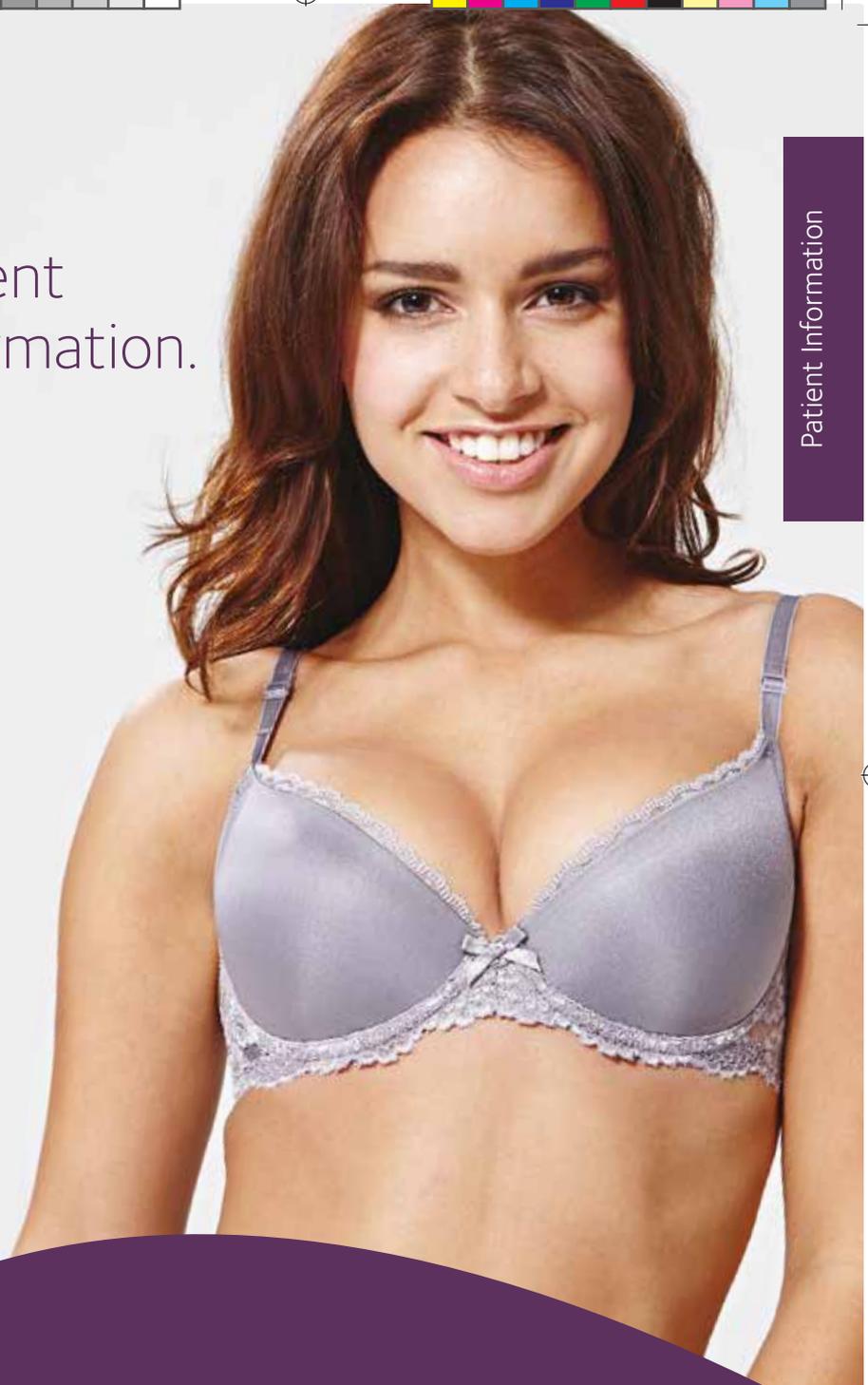




Patient  
Information.

Patient Information



EUROSILICONE™





## Your body, your decision.

So you're thinking about breast surgery, and the prospect of a confident new you is exciting. Before you can make an informed decision, there's much to research and consider.

Over the following pages, you can learn all about breast surgery. There's information about implants themselves, what happens during surgery, what to expect, and the risks to be aware of.

You should discuss all options with your surgeon, who will be able to advise you on the results you can expect based on your individual body type. You should of course ask your surgeon about any questions you may have.

For more information visit [www.eurosilicone.com](http://www.eurosilicone.com).

# Anatomy

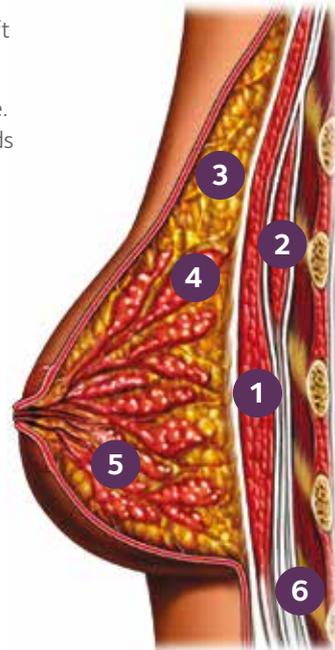
A woman's breast represents her beauty, femininity and sexuality.

The breast consists of milk ducts and glands surrounded by fatty tissue and covered by skin.

The fatty tissue gives the breast its soft feel and shape.

Skin elasticity also affects breast shape. Pregnancy (during which the milk glands are temporarily enlarged) and the inevitable effects of gravity over time stretch the skin envelope and change breast shape.

- 1. Pectoralis Major Muscle
- 2. Pectoralis Minor Muscle
- 3. Fatty Tissue
- 4. Milk Lobes, Glands
- 5. Milk Ducts
- 6. Ribs



## Important considerations

Choosing the right surgeon is one of your most important choices.

You will want to find a surgeon who understands your desires and who can provide you with pre-operative planning, so that you are fully informed at each step of the process.

When consulting with your surgeon, you should ask him/her the following questions:

- Can the surgeon show me before and after pictures of his/her own work?
- What are reasonable results for me to expect?
- What are the risks and complications associated with having breast implants?
- How many additional implant-related operations can I expect over my lifetime?
- How will my breasts look if I choose to have the implants removed without replacement?
- Which shape, size, texture of implants, incision site and placement site is recommended for me?
- How should I prepare for surgery?
- Will my ability to breast-feed be affected?
- How can I expect my augmented breasts to look over time?
- How will my augmented breasts look after pregnancy and breast-feeding?
- What are my options if I am dissatisfied with the outcome of my surgery?

## Living with breast implants

- 1 You should be aware when choosing breast augmentation, that you may require additional procedures over time, as well as further consultations with your surgeon.<sup>1,2</sup>  
.....
- 2 Your breast implants will need to be replaced during the course of your life. Implants are not lifetime devices and are subject to wear and tear like any other implant device e.g. tooth fillings, heart valves, hip joints.<sup>3</sup>  
.....
- 3 Many of the changes to your breasts will be permanent. Should you opt to have your implants removed later in life, you may need to have additional procedures to correct wrinkling, sagging and other breast changes.  
.....
- 4 Breasts will sag with time, age and subsequent pregnancies.  
.....
- 5 It is more difficult to perform a mammography on a patient with breast implants, occasionally requiring additional tests such as MRI and ultrasound.<sup>4</sup>

## Breast implants

Backed by years of continuous Research & Development, Eurosilicone offers a comprehensive range of breast implants that allow your surgeon to use the most appropriate implants.



### Choice of the gel

The gel in your breast implants is important and will help to determine the look and feel of your breasts.

Silicone gel filled breast implants are soft and have a natural look. Gel breast implants are also the most frequently used.

### Choice of the consistency

Eurosilicone's range of silicone gel filled breast implants offers a choice of two different consistencies.

Your surgeon will have the opportunity to choose between soft cohesive gel and natural cohesive gel to meet your expectations.

### Choice of the shape and profile

Eurosilicone breast implants exist in two different shapes: round and anatomical. Eurosilicone breast implants are also available in different sizes and profiles to fit with your body characteristics and personal expectations.

### Choice of the shell

Eurosilicone breast Implants are available with a smooth or textured surface of the shell.

They are made with a shell of silicone, which incorporates a barrier layer. Eurosilicone shells are engineered for strength, longevity and reduced gel diffusion.

Your surgeon will explain these options to you in detail. Rely on their knowledge and experience to select the most appropriate breast implant, but do remember that patients who are actively involved in choosing the implant size are more likely to be satisfied with the surgical results.

## Placement of implants

Talk to your surgeon about the precise placement of the breast implants in detail. You will want to know the result to expect and optional choices available.

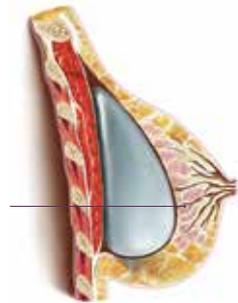
The placement of the implants mostly depends on the thickness of your subcutaneous tissue.

With a subglandular approach, the implant will be placed on top of the pectoral muscle and below the mammary gland. Generally, a subglandular approach allows for less discomfort and a quicker return to activities.

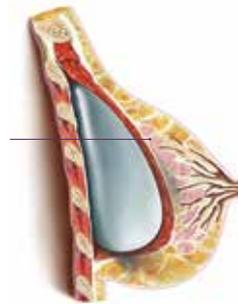
With a submuscular approach the implants will be placed behind the pectoral muscle. Generally, a submuscular approach gives the implants an extra layer of tissue coverage and may give less interference with mammographic examination of the breasts.

You should discuss the advantages and disadvantages of the implant placement selected for you with your surgeon.<sup>5</sup>

Subglandular  
Mammary gland  
and milk ducts



Submuscular  
Pectoral muscle



## Incision points

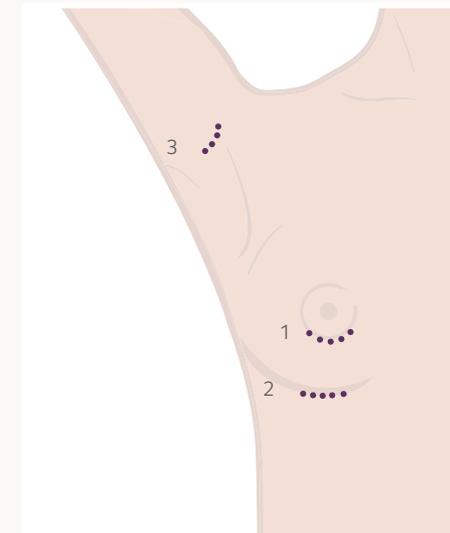
Discuss the exact location of any scars resulting from the operation.

With a peri-areolar incision, the scar will be around your areola. This incision is hidden to some extent by the colour change at the edge of the areola.

With a sub-mammary incision, the scar will be located in the inframammary fold below your breast. This incision is hidden by the slight droop of the breast.

With a trans-axillary incision, the implants are inserted through an incision in the armpit.

You should discuss the advantages and disadvantages of the incision site you are considering with your surgeon.



1. Peri-areolar
2. Sub-mammary
3. Trans-axillary

## Frequently Asked Questions:

### What is breast augmentation?

Breast augmentation is an aesthetic surgical procedure performed to increase the size and alter the shape of breasts using breast implants, for reasons including:

1. Enhancing the body contour of a woman who feels her breasts are too small.
2. Correcting a reduction in breast volume following pregnancy.
3. Balancing a difference in breast volume.

### Who is not eligible for breast implants?

Breast implants are contra-indicated for women who:

1. Have an infection present in their body.
2. Have an auto-immune disease.
3. Are pregnant or breastfeeding.
4. Have a pre-existing malignant cancer of the breast.
5. Are undergoing treatment for a pre-existing malignant cancer of the breast.

### Who is the best candidate for breast augmentation?

The best candidate for breast augmentation is the patient with realistic ideals, as the desired result is breast improvement, not perfection.

There is no guarantee that your results will match those of other women. Your results will depend on many individual factors, such as your overall

health (including age), chest structure, breast/nipple shape and position, skin texture, healing capabilities (which may be slowed by smoking, alcohol and various medications), tendency to bleed, previous breast surgery, surgical team's skill and experience, type of surgical procedure and type and size of the implant.

Before opting for breast augmentation, discuss your expectations with your surgeon, to ensure you will be satisfied with the result.

### What is silicone?

It is important to understand the differences between silicon and silicone. Silicon is a common mineral chemical element and the second most abundant element in the earth's crust.

Silicone is a man-made polymer containing chains of Silicon-Oxygen-Carbon compounds. The most frequent is Poly-Dimethylsiloxane (PDMS). Depending on their structure, silicones can be liquid, gel or solid.

### Is silicone safe?

Breast augmentation using silicone implants was banned by the FDA (Food and Drug Administration in America) in 1992 due to concerns about the safety of silicone. The restrictions have since been lifted and the Institute of Medicine of the Academy of Sciences has declared the implantation of 'silicone' breast implants to be safe.

### Do Eurosilicone implants contain latex?

Eurosilicone implants are composed of medical grade silicone gel and elastomer. Eurosilicone does not use latex or natural rubber in the manufacturing or primary packaging of its implantable products.

### Is breast implant surgery painful?

The pain associated with breast implant surgery depends upon which specific surgery you choose to undertake, whether you choose submuscular or subglandular placement and your individual reaction to the surgery. Generally, post surgical swelling is to be expected, as well as some pain and discomfort.

### How long will the procedure take?

The procedure is routinely performed under general anesthesia and will last 1 to 2 hours depending on the extent of the breast augmentation surgery.

To ensure the highest standard of personalised patient care, you will be required to spend the appropriate time before and after the surgery within the clinic/hospital, allowing time for pre-operative procedures and post-operative care.

### How long will I spend in hospital?

The extent of the surgery will determine the length of stay in the hospital, but you are likely to be discharged the same day as the surgery is performed, depending on

your general health and your surgeon's preferences. It is recommended that you arrange for someone to drive you to the clinic/hospital and collect you upon discharge.

### Do breast implants interfere with mammograms?

You should be aware that breast implants may interfere with the detection of cancer and that breast compression during mammography may cause implant rupture.

Interference with mammography by breast implants may delay or hinder detection of breast cancer either by hiding suspicious lesions or by making it more difficult to include them in the image (x-ray, ultrasounds). Implants increase the difficulty of both taking and reading mammograms.

You should tell the radiological technologist about the presence of implants before mammography is performed.<sup>4</sup>

### What about breast feeding?

Women of childbearing age should know that they may not be able to breast feed after breast augmentation. Some women who undergo breast augmentation can successfully breast feed and some cannot. It is important to discuss the options of breast feeding with your surgeon prior to your operation.<sup>6</sup>

## Possible complications

All surgical procedures can involve the risk of complications such as infection, swelling, redness, bleeding and pain. There are also possible risks of complication linked to breast implant surgery. You should discuss the whole procedure and all risks with your surgeon so that you are fully informed.

### Rupture

Implant rupture can occur immediately or slowly over a period of days. If your silicone gel implant ruptures, you might notice a slight change in the size or shape of your breast. Or you might feel pain or tenderness, swelling, numbness, burning or tingling. It is also possible to have a 'silent rupture,' where you don't have any symptoms at all and you don't realize that your implant has broken. Some implants may rupture in the first few months after being implanted and some rupture after several years.

Causes of rupture include damage by surgical instruments during surgery, capsular contracture, closed capsulectomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging and unknown/unexplained reasons.

You should also be aware that the breast implant may wear out over time and rupture. Ruptured implants require additional surgery to remove and to possibly replace the implant.<sup>7</sup>

### Capsular contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle).

Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant and/or movement of the implant.

Additional surgery is needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries.<sup>8</sup>

### Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or

capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain.

### Additional surgery

You should understand there is a high chance that you will need to have an additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting and calcium deposits can require removal of the implant.

Many women decide to have the implant replaced, but some women do not. If you decide not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

### Dissatisfaction with cosmetic results

Dissatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity and hypertrophic scarring (irregular, raised scar). Careful surgical planning and technique can minimise but not always prevent such results.

### Infection

Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation.

However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues.

If an infection does not respond to antibiotics, the implant may have to be removed and another implant may be placed after the infection is resolved.

In rare instances, toxic shock syndrome has been noted in women after breast implant surgery and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment for this condition.<sup>9</sup>

### Hematoma/Seroma

Hematoma is a collection of blood inside a body cavity and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain and bruising may result.

If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast.

While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing.

A small scar can result from surgical draining. Implant rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

Changes in nipple & breast sensation  
Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breastfeeding below).

#### Breastfeeding

At this time it is not known if a small amount of silicone may diffuse (pass through) from the breast implant and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant.

Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants.

#### Calcium deposits in the tissue around the implant

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer.

#### Delayed wound healing

In some instances, the incision site takes longer to heal than normal.

#### Necrosis

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis.

Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking and excessive heat or cold therapy.

#### Extrusion

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

#### Breast tissue atrophy/ Chest wall deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement. In addition to these common complications, there have been concerns with rarer diseases, of which you should be aware.

#### Connective tissue disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature of small numbers of women with implants.

A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.<sup>10</sup>

#### Cancer

Published studies indicate that breast cancer is no more common in women with implants than those without implants.<sup>11</sup>

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## Glossary

**Areola:** The dark skin that surrounds the nipple.

**Axillary:** Indicates the location of one of the possible incisions for breast augmentation, namely, under the arm.

**Capsular Contracture:** A hardening of the tissue surrounding the breast after breast augmentation.

**Capsulectomy:** Total or partial removal of the capsule surrounding the implant and will usually involve the replacement of the implant.

**Cohesive:** The state of uniting or sticking together. As in cohesive silicone of a thick consistency which does not leak in the event of a rupture. Cohesive gel implants are breast implants that have a silicone rubber shell and are filled with cohesive silicone gel material. Eurosilicone offers 2 types of gel: the more cohesive called "Natural" and a softer gel called "Soft Cohesive".

**Endoscope:** Surgical instrument consisting of a long, narrow, lighted tube with a camera. Can be rigid or flexible and has a wide range of uses in medicine. It can be used to facilitate the insertion of breast implants (particularly the axillary approach). Use of an endoscope is called endoscopy.

**Hematoma:** A mass of usually clotted blood that forms in a tissue, organ, or body space as a result of a broken blood vessel.

**Inframammary:** Also called the "crease" or "fold". Underneath the breast. Indicates the location of one of the possible incisions for breast augmentation, namely, under the breast.

**Lumpectomy:** Excision of a breast tumor with a limited amount of associated tissue.

**Mammography:** X-ray of the breast.

**Mammoplasty:** Plastic surgery of the breast, whether by enlargement (augmentation mammoplasty) reduction (reduction mammoplasty) or lift (mastopexy).

**Mastopexy:** Breast lift.

**Pectoralis major:** The major muscle of the chest or "pecs"

**Peri-areolar:** Around the areola, this is the dark area around the nipple on the breast. Indicates the location of one of the possible incisions for breast augmentation, namely, around the lower one-third to one-half of the areola.

**Pocket:** A cavity made in the body by dissection and tissue expansion to make way for implant placement.

**Ptosis:** Sag or sagginess. There are several levels of ptosis.

**Rippling:** The appearance of waves or wrinkles in the breast.

**Seroma:** a collection of the watery portion of the blood in the tissues due to trauma, surgery, injury or disease. Looks like a swollen area, with no blood, can persist for months and can cause scar tissue.

**Smooth:** Type of breast implant, the exterior surface of which is smooth.

**Subglandular:** Under the breast tissue or gland. One of the locations for breast implant placement. Also known as above the muscle because placement is above the pectoralis muscle but below the breast tissue.

**Submuscular:** Under the muscle. Another location for placement of the implant, i.e. under the pectoralis muscle. Also called «subpectoral».

**Textured:** Type of breast implant in which the outer surface, or shell, is rough and/or irregular instead of smooth.

## Patient Informed Consent Form.

There are a number of risks associated with breast implants and these will have been discussed with your surgeon to ensure that you are fully informed before consenting to the surgical procedure. There are certain risks particularly associated with breast implants, including (but not restricted to) capsular contracture and implant rupture, as well as the risks involved in any surgical procedure. It is also important to be aware that some of the risks are longer term, as they may arise some time after the implantation procedure. The Patient Information Booklet that you were given contains information about the risks and may have formed the basis of your discussion with your surgeon. This document is available in PDF format from our website [www.eurosilicone.com](http://www.eurosilicone.com).

Having considered the risks and discussed these with your surgeon, the purpose of this form is for you to indicate your understanding of the risks and to provide your consent to proceed with the breast implant surgery.

You should only provide your consent if you accept ALL of the following statements:

- I have read the "Patient Information" booklet, discussed it with my surgeon and fully understand all the information contained in the text.
- I accept and fully understand that the risks associated with breast implants and surgery cannot be completely predicted.
- It is my choice to proceed with breast implant surgery as I have concluded that the expected benefits outweigh any potential risks.
- Furthermore, I commit that I have fully informed my surgeon of all details of my past and present medical history including all conditions that could possibly contra-indicate this type of surgery so as not to increase the risks of operative, post-operative or long-term complications.
- My breast implants are not lifetime devices and reoperation will be required at some point.

I intend to have Eurosilicone Implants

(Please tick)

Name of patient (in capitals)

Name of surgeon (in capitals)

Date and signature (patient)

Date and signature (surgeon)

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