

## PATIENT INFORMATION LEAFLET

Dear **Patient**,

You receive this Patient Information Leaflet from your surgeon, as you have expressed an interest in plastic breast surgery with implants.

As with any surgical procedure, possible complications may occur in association with breast augmentation or breast reconstruction procedures with implants, as a result of individual health conditions, medication, surgical technique, and postoperative care. Some risks, such as anesthesia, medication and infection, are general, and are present with any surgical procedure, others are specific to breast surgery with implants. Breast implants are not lifetime devices.

There are alternatives for breast plastic surgery that do not include the use of implants, such as the use of autologous fat tissue or muscle flap transplants. Your surgeon should inform you fully and comprehensively about the available procedures and their related risks and benefits, prior to your decision. You should receive educational material, take time to think about this information, discuss it with your surgeon and ask questions, to make sure you have fully understood all the risks and benefits. You should also feel free to ask for a second opinion: if you are not convinced, do not feel pressured to undergo any procedure.

At POLYTECH we believe in providing comprehensive safety-related information to patients: your decision should be personal and informed. Please read this Leaflet carefully.

In your final decision you should take into account both risks and benefits of breast surgery with implants. Your express and unconditioned decision in favor of breast plastic surgery with implants must be recorded in the Informed Consent form, provided to you by your surgeon.

Please note different implant types have different safety and performance profiles. For example, smooth implants have a very high rate of capsular contracture, but are not currently associated with BIA-ALCL. Please read further for more details on these topics.

In case you opt for breast plastic surgery with implants, after the procedure you will receive an *Implant Passport* from your surgeon. This *Implants Passport* includes information about your implants as well as our contacts, in case you need more information or need to report an issue: please always keep this document safely with you.

After breast implants surgery, it is important that you follow your surgeon's recommendations, and that you undergo regular check-ups every six months or annually. Also, for your own safety you should inform your physicians and the person performing your mammography about your implants.

*Please note that breast implants have a limited lifespan. An implant will need to be removed or replaced, which will then require additional surgery.*

If you are experiencing problems like swelling, aesthetic impairment or pain following breast implant surgery, you should immediately inform your surgeon, and consider the available solutions.

We wish you all the best in this journey and we remain available for information and support, whatever direction you choose.

*The POLYTECH Team*

## PATIENT INFORMATION LEAFLET

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### 1. BREAST IMPLANTS

There exist different types of breast implants on the market. Implants may vary by shape, filling and surface type.

Shape		Filling		Surface		
Round	Anatomical	Saline solution	Silicone gel	Smooth	Textured	Polyurethane-covered

Implants also vary in projection, which indicates how much the implant projects forward, and in volume, which is the quantity of three-dimensional space enclosed by a closed surface. Volume may be expressed in milliliters (ml) or in cubic centimeters (cc).

#### 1.1. INFORMATION ON POLYTECH IMPLANTS AND HOW TO IDENTIFY THEM

The POLYTECH range of breast implants includes the following shapes:

**Même®** – a silicone gel-filled implant with a round base and a round profile

**Replicon®** – a silicone gel-filled implant with a round base and anatomical profile

**Opticon®** – a silicone gel-filled implant with an oval short base and anatomical profile

**Optimam®** – a silicone gel-filled implant with an oval oblong base and anatomical profile

The POLYTECH range of breast implants includes the following fillings:

**Sublime Line®** - these breast implants are filled with **EasyFit Gel™**.

**Diagon\Gel® 4Two** – these breast implants are filled with two different gels: the softer **EasyFit Gel™** at the posterior and the firmer **Shapar Gel™** at the anterior.

The POLYTECH range of breast implants currently available in Australia include the following surfaces:

**POLYsmooth®** – a smooth surface, available for round-profile implants.

**MESMO®sensitive** – this implant shell has a fine micro-textured surface.

**POLYtxt®** – this implant shell has a micro-textured surface.

## **POLYTECH breast implants are available with different projections and different volumes**

POLYTECH implants are available with up to 4 projections – low, moderate, high and extra high – and in a volume range starting from 50ml up to 700ml. Volumes larger than 700ml are treated as custom made implants, which means your surgeon has to specifically and expressly attest in a dedicated form the choice of such volume and size and its suitability to you and your conditions.

**A complete list of the above mammary implants, including of their product reference number, is available as Appendix A.**

## **What are our implants made of?**

Breast implants by POLYTECH are made of medical grade silicones, approved for long-term implantation in the human body. Our breast implants consist of a silicone elastomer shell, filled with silicone gel.

In medicine, silicone (not to be confused with silicon, the semi-metal material which microelectronics are made of) is used as a component of numerous products, e.g. probes, catheters, coatings of puncture needles and pacemakers, gloves and wound dressings. In soft-tissue surgery, silicone implants are used for body contour correction.

The first production process for silicone polymers was patented in 1958. Silicone, or as chemists call it, polydimethylsiloxane, is produced in different formulas: as silicone elastomer, silicone gel and silicone oil.

Silicone does not contain any additives, especially no softeners.

## **1.2. WHY ARE DIFFERENT SURFACE TYPES AVAILABLE?**

The first breast implants were manufactured in the 1960s and had a smooth surface. A polyurethane foam covering was introduced in the 1970s to minimize the event of capsular contracture as well as implant dislocation and rotation. Textured implants were introduced in the late 1980s, to mimic the effect of the polyurethane layer.

But what is capsular contracture? As part of the body's natural reaction, a capsule of connective tissue is formed around any foreign body inserted into the tissue, including around breast implants. The undesired tightening of this capsule (capsular contracture or capsular fibrosis) can result in changes to the shape as well as to the position of the implant, and thus the shape of the breast. Additionally, the capsule can become very hard and cause pain. Capsular contracture is the most common complication of breast-implant surgery and it is classified along the Baker scale (See also Complications).

<b>Baker scale for capsular contracture</b>	
Grade I	The breast is normally soft and appears natural.
Grade II	The breast is a little firm and appears natural.
Grade III	The breast is firm and appears abnormal.
Grade IV	The breast is hard, painful to the touch, and appears abnormal.

A capsular contracture may never occur at all, or it may occur after weeks, months or years. It cannot be foreseen if or when a capsular contracture will occur and, if it does, how pronounced it may be.

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The rates of occurrence of capsular contracture, as well as of other complications such as rotation and dislocation, vary in relation to the implant surface:<sup>1</sup>

	Smooth implants	Textured implants
Capsular contracture rate	30-50%	15-30%

## 1.3. CHOICE OF IMPLANT AND AESTHETIC OUTCOME

Your body is unique. When choosing an implant, it is important to consider your individual needs and characteristics: volume and size should match your physique, so the implants are comfortable over time.

During the consultation, speak openly with your surgeon and communicate your personal wishes and goals for the procedure. This is the only way to create realistic expectations and minimize the chances of unsatisfactory result. Take your surgeon's opinion seriously. A good surgeon has the know-how and experience to recommend the breast implants best suited for you.

When considering a reoperation due to an unsatisfactory result, please note that the chances for complications increase with revision operation.

## 1.4. CERTIFICATION OF MAMMARY IMPLANTS

Mammary implants are medical devices. Mammary implants produced in the European Union are certified according to European medical device directives, which identifies them as Class III devices. Class III is the class for those devices that due to the length and extent of their invasiveness in the human body, need to fulfil the strictest requirements of all classes. They may be certified also according to other alternative or concurring regulations, for sale in other countries outside the European Union.

As Class III implantable devices, breast implants are subject to regular testing. Materials, product development, production, quality control, sterilization and packaging are subject to very strict regulations and must fulfil a set of international standards. POLYTECH Health & Aesthetics' product have the required CE mark for the design of mammary implants, as well as for the ongoing quality management system for their development, manufacturing, final inspection and distribution, according to the current standards ISO 13485:2016 and Annex II of the Medical Device Directive 93/42/EEC.

In Australia, breast implants are also classified as high risk devices; together with all other devices, they need to be registered in the Australian Register of Therapeutic Goods to be legally sold in the Country.

## 2. BREAST SURGERY WITH IMPLANTS

### 2.1. INDICATIONS AND CONTRAINDICATIONS

Breast implants are used in breast plastic surgery for cosmetic purposes, for reconstruction and for implant replacement. Make sure to thoroughly discuss your wishes and your needs with your surgeon.

You should discuss your past and current health conditions with your surgeon, as some circumstances or diseases may affect your eligibility for breast surgery with implants.

Current anti-coagulation therapy, impaired blood circulation or coagulation (e.g. due to diabetes, smoking, radiation exposure), impaired wound healing, a current active infection, soft-tissue pathologies and autoimmune connective tissue diseases, among others, require precaution when electing breast implant surgery and may constitute contraindications.

Contraindications include:

Mental instabilities, repeated attempts or failures of contour correction, clinically persistent infections or systemic diseases, expected allergies or extraordinary immune response to implants; abscesses, cysts or tumors in the area of implants, especially cancer and recurrent metastases (e.g. persistent or intermittent mammary cancer), advanced fibrocystic diseases; severe radiation injuries in the prospective area of implants; heavy burn scars in the prospective area of implants; insufficient tissue covering in the prospective area of implantation (e.g. after preceding breast reduction) or reduced vascularization; existing costal injuries pregnancy, breast feeding; inflammation in the prospective area of implantation; a suppressed immune system.

Your surgeon should inform you fully and comprehensively about the alternatives to surgery with breast implants.

Equally, if you opt for breast surgery with implants, in the future you should inform your doctors, surgeons and technical medical personnel of the presence of the implants.

## **2.2. IMPLANT LIFE TIME**

Breast implants are not lifetime devices. The longer you have breast implants, the more likely it is that complications will occur and you will need to have them removed. There is no guarantee that you will have a satisfactory cosmetic outcome from any reoperation. Complications may lead to one or more reoperations. The risks of a reoperation are higher than the risks of the first surgery. The operations performed during a revision surgery depend on the complication. They include:

- Implant removal, with replacement
- Implant removal without replacement
- Capsulectomy or removal of the capsule (the scar tissue around the implant)
- Capsulotomy or surgical incision to loosen the capsule
- Scar or wound revision, such as surgical removal of excess scar tissue
- Drainage of a hematoma or seroma (a collection of blood or of fluid) by a needle or tube
- Repositioning of the implant by surgically opening the incision and moving the implant
- Biopsy by inserting a needle through the skin to collect a sample of tissue or lump removal by surgically removing a lump.

Everybody reacts individually to a foreign body; therefore, it is not possible to foresee a standard lifetime of an implant. The expected lifespan was assessed by evaluating clinical data from other silicone breast implants that are considered equivalent. Technical advances have resulted in improved quality and a significant reduction in the incidence of implant ruptures compared to earlier generation implants. Of course, the likelihood of an implant rupture increases with the age of the implant. Based on a variety of studies using MRI, the rupture frequency varies from 0.5% - 7.7% three years after implantation and rises up to 9.3% six years after implantation<sup>2</sup>. Another study reported an 8% rupture rate for a mean 11-year period after implantation<sup>3</sup>. These figures are estimates for the worst-case scenario, as they are based on imaging results for both confirmed and undetermined ruptures.

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The results include a variety of study cohorts (e.g. primary and secondary augmentations and reconstructions). Therefore, the lifetime rate of POLYTECH implants can be estimated to be approximately 90% after 10 years.<sup>2-4</sup> Abnormal stress and excessive movement or trauma to the tissue surrounding the implant may result in implant rupture (rupture of the implant shell) and necessitate for implant removal.

In the unlikely case of a shell rupture, any leaking gel will be contained by the connective tissue capsule, which forms naturally around the implant. Factors that can result in a rupture of the implant shell include damage to the implant shell during implantation or due to surgical procedures (e.g. biopsies), normal material fatigue of the implant shell, mammographies and complications of capsular contracture. An implant rupture may occur unexpectedly (silent rupture) and you may not notice it. Therefore, you should attend the follow-up examinations recommended by your physician. In case of an implant rupture, we always recommend an implant replacement.

## 2.3. SCREENING DIAGNOSTICS, CONTROLS AND THERAPIES

Silicone implants can interfere with screening techniques and have a falsifying effect on results. Make sure you inform with due advance the medical staff involved about the existence of your implants.

Various methods are used to examine the breast and the implants. Examinations have two main objectives:

1. determine whether malignant diseases of the breast are present (e.g. breast cancer) and
2. study possible complications that may be associated with the use of breast implants (e.g. capsular fibrosis, ruptures of the implant shell, etc.)

Usually, imaging procedures such as mammograms (using X-rays), magnetic resonance imaging (MRI) or ultrasound screening (US) are used for both purposes.

But invasive methods for diagnosis and treatment are also used, such as biopsies, performed to remove conspicuous tissue for subsequent histological examination, or punctures, for example to remove seromas (accumulations of fluid around the implant).

These methods can be negatively influenced by the implant or may have a negative effect on the implant. During biopsies and punctures, there is always the risk of damaging the shell of the implant, in a way that will ultimately require implant removal. It is therefore very important that you inform the treating doctor about the implants.

### Imaging procedures:

#### Interference with standard mammogram

A mammogram is performed with a machine that compresses the breast between two plates and takes an x-ray picture of the flattened breast. The flattening allows for a better image and a lower radiation dose.

A mammogram with breast implants is possible, but it may be more difficult to perform due to the following reasons:

- The silicone gel in the implant is opaque under x-rays, thus can hide part of the breast tissue and making it harder to detect calcifications or masses, and the presence of the implants can make it challenging for the technician to properly position and flatten the tissue.
- The pressure from the machine may rupture your implants.

To overcome these challenges a special technique, the Eklund Technique, was developed to allow mammograms to be performed also in women who have breast implants. Make sure you inform the technician about the type and positioning of your implants before the examination. This information is included in your *Implants passport*. An ultrasound or an MRI may be recommended as an alternative screening technique.

## Interference with MRI

Breast implants do not have a negative influence on MRI examinations and the magnetic field used has no negative influence on the breast implants.

However, there are two things to consider:

- MRI examinations are contra-indicated when using certain expanders in a two-stage breast reconstruction after a mastectomy. Make sure you inform the doctor or technician in this case.
- Although MRI examinations are considered the gold standard for detecting shell damage, false-positive or false-negative diagnoses occur.

## Interference with ultrasound screening

Like with mammograms, the sound waves used in an ultrasound examination cannot penetrate the implant. Therefore, with this method only the tissue in front of the implant and the faced implant shell itself can be examined. The opposite implant shell and the tissue behind the implant cannot be imaged. Since the implant is usually placed under the mammary gland or even deeper, under the pectoral muscle, this is not a serious disadvantage for the examination of the breast tissue.

## Interference with self-examination

While implants may make it more difficult for you to perform routine self-examination of your breasts, it is important that you perform such examination at regular intervals for cancer screening. Please see section 2.5. on "Breast Cancer" for further information on self-examination.

## Interference with radiation therapy

Radiotherapy is usually performed with gamma radiation. The interaction of this radiation with the silicone of the implants is comparable to its interaction with the tissue. Therefore, if breast cancer is detected in an implant recipient, the implant does not significantly interfere with radiotherapy. However, the implant is usually removed in the course of oncological treatment.

Another case is radiotherapy in the course of breast reconstruction. If a mastectomy was performed due to breast cancer and then breast reconstruction with implants is to be performed and radiotherapy is necessary, the sequence of the individual measures (expander insert, implant insert, radiotherapy) must be carefully planned and adapted to the circumstances of the individual patient. Even if the dose of radiation used is too low to seriously weaken the stability of the implant, it is known that the risk of complications after radiotherapy is significantly higher than in non-irradiated patients. Studies have shown that the selection of certain implants can significantly reduce these risks. If you are affected, please discuss this point carefully with your treating physician.

## 2.4. COMPLICATIONS

Complications are unfavorable evolutions or consequences of a disease, a health condition, a therapy or a procedure. Following, we have compiled a list of the most common complications, with an explanation and, where appropriate, with recommendations.

If you are experiencing problems, swelling, aesthetic impairment or pain following breast implant surgery, you should immediately inform your surgeon, and consider the available solutions.

In case of problems with your implants, you are encouraged to contact POLYTECH, our local supplier or the local Regulatory body, directly or with the assistance of your surgeon. Reporting of issues assists us in identifying any trends so that action, if necessary, may be taken at the earliest opportunity.

## POSSIBLE COMPLICATIONS INCLUDE:

- Capsular contracture or capsular fibrosis: When any foreign body is placed inside an organism, the physiological reactions include metabolization, expulsion or isolation. In the latter case, a capsule is formed around the foreign body, which is what happens with breast implants in the human body. This capsule can draw tight around the implant and contract. The contraction deforms the implant shape and thus the shape of the breast. Additionally, the capsule can become very hard and cause pain. This complication is referred to as "capsular contracture" and its occurrence rates vary according to implant surface. A significant capsular contracture will result in implant removal (see also Why are different types of implants available).
- Seromas: Seromas develop as an accumulation of serous fluid around the implant, which can lead to pain and excessive swelling of the breast(s). Several reasons can cause seromas: intraoperative or post-operative traumatization, excessive postoperative mobility of the implant or infection. Possible therapies: immobilization, compression, drainage or implant removal, if necessary. Seromas may be early, when occurring immediately after surgery, or late, when occurring several months after surgery. See the section on Anaplastic Large-Cell Lymphoma.
- Pain: Pain may occur in the operated area as well as in the pectoralis and shoulder-arm areas after mammary surgery. Continuous pain may be due to improperly sized or placed implants. Over-sized implants, capsular contracture as well as irritations due to excessive implant movement, may provoke pain. Please consult your surgeon immediately to clarify the cause of pain following an operation.
- Reddening of the skin or "rash": It can be observed in different frequencies with specific indications, depending on the surface structure. This reddening of the skin should not be confused with an infection. It differs from an infection by itching and the absence of systemic infection symptoms. It usually occurs 7 to 10 days after the implantation and can last 2 to 3 weeks. The use of steroids may be necessary.
- Chest wall deformity: The rib cage may be deformed due to the pressure exerted by the implant.
- Calcification: Benign calcification around the implant is possible.
- Infections: Infections can manifest themselves with fever and/or inflammation. Infections in connection with breast implants are very rare: 0.114%.<sup>5</sup> Infections with unclear etiology that occur after breast implantation surgery should be treated immediately. The use of antibiotics, drainage or implant removal may be necessary. Not all infections can be treated while the implant remains in the body. The "toxic shock" syndrome has been reported in extremely rare cases in connection with breast implants.
- Inflammation or irritation: Reactions of the body to an infection or injury showing as redness, swelling, pain.
- Implant rupture: Failure of the integrity of the implant shell. Implant damage (intraoperatively, e.g. by too short incisions, by surgical instruments, or postoperatively, e.g. in case of punctures, biopsies etc.), traumata or material fatigue are, in our opinion, the most frequent reasons. After rupture of a gel-filled implant, the consistency of the silicone gel prevents diffusion. However, it is not guaranteed that the gel remains a complete unity. Ruptures may be noticeable (symptomatic ruptures) or not (silent ruptures). Magnetic resonance imaging (MRI) is the most effective method for detecting silent rupture of silicone gel-filled breast implants.

If a rupture is diagnosed the implant should be replaced.

- **Permeation of silicone:** All modern breast implants are equipped with special barrier layers to prevent the diffusion of silicone particles through the shell. While the passage of low molecular weight silicone components through the shell of the implant cannot be completely excluded, normally, the small amounts of gel remain within the tissue capsule that physiologically grows around the implant.<sup>6</sup>
- **Granuloma:** Granulomas are localized nodular inflammations, which may result from an implant rupture or from silicone permeation. Granulomas of unknown genesis are an indication for a biopsy or for implant removal.

**Swelling of the axillary lymph nodes** Lymph nodes are small structures located all over the body around blood vessels. They are part of the lymphatic system of the body. They can swell and become tender or painful in case of a local infection, an infection affecting the whole body, cancer or immune disorders. Axillary lymph nodes are the lymph nodes located in the armpit and which drain the breast area of fluid. Some patients with breast implants have been found to have enlarged lymph nodes in the arm pit. This is referred to as lymphadenopathy. It has been reported to occur in women with both ruptured and intact silicone gel breast implants. If an enlarged lymph node becomes painful, it may need to be surgically removed. You should immediately report any painful or enlarged lymph nodes to your doctor.

## 2.5. COMPLICATIONS - SYSTEMIC DISEASES AND CANCER:

### Autoimmune and connective tissue diseases

A possible connection between autoimmune and connective tissue diseases and mammary implants has been discussed since the 1980s. Extensive independent studies have shown no connections between silicone gel-filled breast implants and autoimmune disease or connective tissue disease.<sup>7</sup>

### Breast cancer

The extensive studies available show that women with breast implants are not subject to a higher risk of breast cancer than women without breast implants.<sup>8</sup> In other words, a breast implant has no influence on the occurrence of breast cancer. While scientists do discuss the theoretical risks of this disease with implants, breast cancer as a direct result of breast implants has not been observed in human beings nor in studies on animals.

It is important that you undergo all the usual breast examinations, such as self-examination and possible imaging procedures (mammary sonography, tomosynthesis, mammogram, magnetic resonance imaging (MRI) to detect possible breast cancer. Modern imaging techniques such as sonography, MRI or computer tomography (CT) help to find tumors at an early stage.<sup>9</sup>

Make sure to self-examine your breasts at regular intervals. For post-operative self-examination, your physician should instruct you on how to distinguish between the implant and your own tissue to enable you to detect nodules yourself. Do not just touch your breasts, also look for swelling, redness and inflammation, as well as any breast deformities, even if these are not yet painful. If you find any changes, please consult a physician.

### Anaplastic large cell lymphoma (ALCL)

Reports from regulatory agencies and medical literature have shown an association between breast implants and the development of ALCL, resulting in the term BIA-ALCL or Breast Implant-Associated ALCL. This means that women with breast implants may have an increased small risk to develop ALCL. There are several different estimates of the risk to develop BIA-ALCL.

The vast majority of cases in literature concern patients with history of use of textured implants and currently there are no published primary cases with smooth implants.

ALCL is currently classified as a form of non-Hodgkin's lymphoma (NHL) - a cancer of the immune system. It typically presents itself as a late seroma – the accumulation of liquid within the capsule – containing atypical cells, but it may also occur with the formation of a mass. The symptoms may occur well after the surgical incision has healed, often years after implant placement, but there are known cases with a shorter time of occurrence.

ALCL is a rare but serious type of cancer. There are documented cases of death due to the spreading of the disease out of the capsule. When detected early and timely treated, this disease has a positive prognosis.

In most patients, it is treated successfully with surgery to remove the implant and surrounding scar tissue, but in some patients, also treatment with chemotherapy and radiation therapy may be necessary.

**It is very important that you continue to attend regular check-ups and perform self-examination. If symptoms such as swelling, pain or a lump in the implant region occur, you should immediately inform your doctor. In case of suspected BIA-ALCL, they should prescribe tests for its exact diagnosis, including sampling of the fluid around the implant and either a MRI or an ultrasound of the breast. In case BIA-ALCL is confirmed, a team of physicians, including an oncologist, will attend to your treatment and recovery, according to the guidelines approved by the international medical community.**

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of BIA-ALCL.

## **Australian Breast Device Registry**

Ask your surgeon if they contribute to the Australian Breast Device Registry (ABDR). The ABDR records your contact details and the details of your surgery (including the reason for your surgery). Including your details in the ABDR helps track the long-term safety and performance of breast implants. It also helps in notifying you and other patients of any safety concerns related to breast implants. Research reports and other publications that use ABDR data will not contain any identifiable information about you. More information about ABDR data privacy is available on the ABDR website. We encourage you to contribute to the ABDR, but you may choose to opt-out if you wish. **All cases of BIA-ALCL associated with this device should be reported in detail to POLYTECH and it is also recommended that surgeons report them to the competent authorities and to the pertinent breast device registries.**

## **Reporting of incidents**

**Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration'. Ask your surgeon for assistance.**

Please note:

- The website address of the Therapeutic Goods Administration (TGA): <https://www.tga.gov.au/>
- Our POLYTECH contact information: [vigilance@polytechhealth.com](mailto:vigilance@polytechhealth.com)

## Appendix A

Product reference*	Surface	Base	Profile	Projection
10724-XXX	POLYsmooth®	Round	Round	Low
10725-XXX	POLYsmooth®	Round	Round	Moderate
10726-XXX	POLYsmooth®	Round	Round	High
10727-XXX	POLYsmooth®	Round	Round	Extra-high
15725-XXX	MESMO® sensitive	Round	Round	Moderate
15726-XXX	MESMO® sensitive	Round	Round	High
15727-XXX	MESMO® sensitive	Round	Round	Extra-high
15735-XXX	MESMO® sensitive	Round	Anatomical	Moderate
15736-XXX	MESMO® sensitive	Round	Anatomical	High
15737-XXX	MESMO® sensitive	Round	Anatomical	Extra-high
15745-XXX	MESMO® sensitive	Oval short	Anatomical	Moderate
15746-XXX	MESMO® sensitive	Oval short	Anatomical	High
15747-XXX	MESMO® sensitive	Oval short	Anatomical	Extra-high
15775-XXX	MESMO® sensitive	Oval oblong	Anatomical	Moderate
15776-XXX	MESMO® sensitive	Oval oblong	Anatomical	High
20724-XXX	POLYtxt®	Round	Round	Low
20725-XXX	POLYtxt®	Round	Round	Moderate
20726-XXX	POLYtxt®	Round	Round	High
20727-XXX	POLYtxt®	Round	Round	Extra-high
20734-XXX	POLYtxt®	Round	Anatomical	Low
20735-XXX	POLYtxt®	Round	Anatomical	Moderate
20736-XXX	POLYtxt®	Round	Anatomical	High
20737-XXX	POLYtxt®	Round	Anatomical	Extra-high
20744-XXX	POLYtxt®	Oval short	Anatomical	Low
20745-XXX	POLYtxt®	Oval short	Anatomical	Moderate
20746-XXX	POLYtxt®	Oval short	Anatomical	High
20747-XXX	POLYtxt®	Oval short	Anatomical	Extra-high
20774-XXX	POLYtxt®	Oval oblong	Anatomical	Low
20775-XXX	POLYtxt®	Oval oblong	Anatomical	Moderate
20776-XXX	POLYtxt®	Oval oblong	Anatomical	High
20777-XXX	POLYtxt®	Oval oblong	Anatomical	Extra-high
21631-XXX	POLYtxt®	Round	Anatomical	High
21632-XXX	POLYtxt®	Round	Anatomical	Extra-high
21641-XXX	POLYtxt®	Oval short	Anatomical	High
21642-XXX	POLYtxt®	Oval short	Anatomical	Extra-high

\* Where "XXX" indicates the volume. Each product reference is available in several volumes, from a minimum of 5 to a maximum of 20, in a range from 45 to 1100 ml. Volumes above 700 ml are manufactured as Custom Made products.

<sup>1</sup> Handel, N., Cordray, T., Gutierrez, J., Jensen, J.A. (2006) A long-term study of outcomes, complications, and patient satisfaction with breast implants. *PRS* 117, 757 et seq.; Kjoller, K., Holmich, L.R., Jacobsen, P.H., Friis, S., Fryzek, J., McLaughlin, J.K., Lipworth, L., Henriksen, T.F., Jorgensen, S., Bittmann, S., Olsen, J.H. (2002) Epidemiological investigation of local complications after cosmetic breast implant surgery in Denmark. *Annals of Plastic Surgery* 48(3), 229-237; Malata, C.M., Feldberg, L., Coleman, D.J., Foo, I.T., Scarpe, D.T. (1997) Textured or smooth implants for breast augmentation? Three-year follow-up of a prospective randomised controlled trial. *British Journal of Plastic Surgery* 50(2), 99-105; Tebbetts, J.B. (2001) A surgical perspective from two decades of breast augmentation. *Clinics in Plastic Surgery* 28(3), 425-434; Young, V.L., Nemecek, J.R., Nemecek, D.A. (1994) The efficacy of breast augmentation: breast size increase, patient satisfaction,

and psychological effects. *Plast. Reconstr. Surg.* 94, 958-969; Hohlweg-Majert (1991) AWO-Jahrestagung, Baden-Baden; Spear, S.L., Mesbahi, A.N. (2007) Implant-based reconstruction. *Clinics in Plastic Surgery*.

<sup>2</sup> Cunningham, B. (2007) The Mentor Core Study on silicone MemoryGel breast implants. *Plast. Reconstr. Surg.* 120(7 Suppl 1), 19S-29S.

<sup>3</sup> Spear, S.L., Murphy, D.K., Slicton, A., Walker, P.S., Inamed Silicone Breast Implant U.S. Study Group (2007) Inamed silicone breast implant core study results at 6 years. *Plast. Reconstr. Surg.* 120(7 Suppl 1), 8S-16S.

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