





Implants of Excellence

You are just about to make the very personal decision of having breast implants. You have reflected about the surgery and also about which implants to choose.

With an implant from POLYTECH Health & Aesthetics and your participation in the program Implants of Excellence you are choosing highest product quality combined with highest personal safety.

Highest product quality

Breast implants from POLYTECH Health & Aesthetics are C€-marked as medical devices.

Regular testing shows that the quality of the implants always meets the norms and often exceeds the requirements of many of the standards.

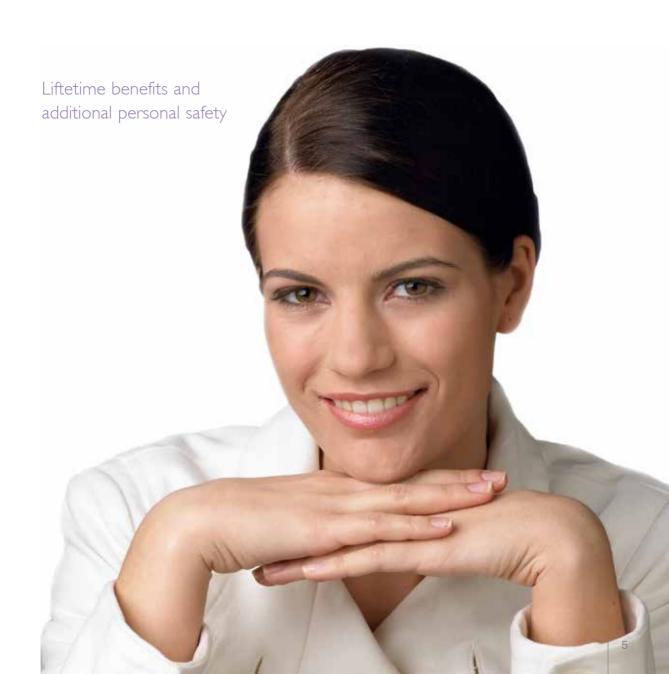
Consistent safety from the experts of silicone-gel-filled breast implants – maximum quality for your beauty.

Highest personal safety

With Implants of Excellence we offer an extended warranty for our POLYTECH Health & Aesthetics implants. Taking part in the program, you will enjoy lifetime benefits and additional personal safety:

- In case of rupture of the implant shell, we provide a lifetime exchange guarantee for your POLYTECH Health & Aesthetics silicone-gel-filled breast implant. * (see page 15)
- Additional benefits apply to POLYTECH Health & Aesthetics silicone-gel-filled breast implants with micropolyurethane coating (Microthane®) used for a cosmetic augmentation: In case you become subject to a capsular contracture or implant dislocation / rotation with this type of implant, we offer an additional product exchange guarantee for up to 10 years after implantation.** (see page 15)

The surgery must be carried out by a qualified surgeon under consideration of the instructions for use of implants from POLYTECH Health & Aesthetics and according to state-of-the-art surgical techniques.



How to participate in the program Implants of Excellence

With Implants of Excellence we document the high product quality of our POLYTECH Health & Aesthetics silicone-gel-filled breast implants, and this documentation increases your safety.

After you have had your implant surgery, please fill in your personal registration form (see p.13), fax it, or scan it and send us an e-mail to ioe@polytechhealth.com, or dispatch it to us by regular mail. Or simply register online at:

www.polytechhealth.com, Warranty, Registration Implants of Excellence

If the registration was successful, you will receive by regular mail your personal registration card and further information on the program Implants of Excellence.

Once a year, we will ask you to answer a few easy-to-answer questions about your satisfaction with the implant/s and your well-being via the our website online module:

www.polytechhealth.com, Warranty, Annual Survey

Then your Implants of Excellence warranty will be extended for another year within the defined period.



The Annual Survey is initiated every year around April or May. We contact all patients registered until 30 March of the year before. You will receive your personal access data for the respective Annual Survey via e-mail. If you have not received your e-mail until the end of May and think that we may have left you out, please contact us via ioe@polytechhealth.com.

Please be aware of the fact that the extended warranty program will only continue after our receipt of your replies via the online module.

If you wish to discontinue participating in the program Implants of Excellence, you can do so at any time by sending us a written withdrawal. Alternatively, you can stop participating in the Annual Survey. This will terminate your claim to the extended warranty automatically.

By registering personally and voluntarily with the Implants of Excellence program, you allow POLYTECH Health & Aesthetics to use the information you provide for statistical analysis. We are obliged to handle personal data strictly confidential. All data will exclusively be used for statistical analysis. POLYTECH Health & Aesthetics reserves the right of publication of the statistical analysis.





What are the benefits of the program Implants of Excellence?

For the lifetime of the patient, we guarantee the exchange of a silicone-gel-filled breast implant manufactured by POLYTECH Health & Aesthetics in the proven case of a damage to the shell integrity (rupture).* (See page 15)

For silicone-gel-filled breast implants with micropolyurethane coating (Microthane®) that are used for cosmetic augmentation, we guarantee the free-of-charge exchange of the concerned implant in case of a capsular contracture Baker grade III or IV for up to ten years after implantation. ** (see page 15)

For silicone-gel-filled breast implants with micropolyurethane coating (Microthane®) that are used for cosmetic augmentation, we additionally guarantee the free-of-charge exchange of the concerned implant in case of an implant rotation or dislocation for up to ten years after implantation.** (see page 15)

Exchange implants for your lifetime.

The Implants of Excellence program exclusively covers the original implant to be exchanged by an implant of the same type from POLYTECH Health & Aesthetics. The size may be chosen freely. Claims for money instead of an implant for exchange cannot be asserted.

In return for the information on your well-being once a year, you will receive an update on the information we retrieve from evaluating the accumulated replies. The program Implants of Excellence provides a unique opportunity for you to participate in and benefit from documented safety.

Implants of Excellence – because it is your body, your beauty, your decision.



What happens if you suspect you need to make a claim to your Implants of Excellence guarantee?

Should you be diagnosed with shell rupture or, in case of a micropolyurethane-coated implant, with rotation, dislocation or capsular contracture Baker grade III or IV, please contact us (ioe@polytechhealth.com) so we can agree on the course of action to follow.

Immediately after the explantation of the implant or not later than four weeks after the surgery, your surgeon has to inform POLYTECH Health & Aesthetics in writing that you have undergone surgery to explant the breast implant. Also s/he needs to send us a detailed report and the explanted implant for an in-depth examination to the following address:

POLYTECH Health & Aesthetics GmbH Altheimer Strasse 32 64807 Dieburg Germany

Please be aware of the fact that the diagnosis as well as the explantation surgery have to be executed by the same surgeon who originally performed the implantation (alternatively: in the same clinic).* (see page 15)

For online registration please go to: www. polytechhealth.com Warranty, Registration Implants of Excellence

Registration for the program Implants of Excellence

Name and address of the patient:		Name and address of the surgeon who performed the implantation:
Family name, first name ☆		
Street û		
Postal code, city, country û	RIGHT	
Implant/s reference number/s REF û	RIGHT	Clinic û
Implant/s serial number/s SN ⊕		Name of surgeon ⊕
Implantation date û		Street ⊕
eMail address û		Postal code, city, country û
Indication:	Implant position:	Approach for the implantation:
☐ Breast enlargement	☐ Above the breast muscle	☐ Below the breast ☐ Through the armpit
□ Reconstruction□ Implant exchange	Below the breast muscleOther position:	□ Around the nipple □ Other approach:
Please send this registration form to: POLYTECH Health & Aesthetics GmbH Implants of Excellence Altheimer Strasse 32 64807 Dieburg Germany		I have read the information brochure about the extended warranty program Implants of Excellence and I herewith personally register for this program and agree to the terms:
If you have any questions, please do not hesitate to contact us: Postal address: see above		
Fax: 0049 (0)6071 9863-30 eMail: ioe@polytechhealth.com		Signature of the patient, date, place
(POLYTECH Health & Aesthetics GmbH is obliged to treat personal data as strictly confidential. Your eMail address will be accessed only to clarify any further questions and to forward the annual information brochure. All other data will exclusively be used for statistical analysis. POLYTECH Health & Aesthetics GmbH reserves the right of publication of the statistical analysis.)		Your personal registration card shall be send: ☐ to the address of your surgeon ☐ to your home address



Conditions of Participation in the "Implants of Excellence" extended warranty program

- 1. To be eligible to make claims from the guarantee of the program Implants of Excellence, you must participate in the program Implants of Excellence and register. Prior to registering, please read our brochure explaining the program. After the implantation surgery, you can perform your registration on-line via our website or by sending us the completed registration form (p. 13 in this brochure). To register you need your implant passport, which you will receive from your surgeon after the implantation.
- 2. The extended warranty program Implants of Excellence is valid only for POLY-TECH Health & Aesthetics standard breast implants (as listed in our currently valid product catalog), and includes the following services:
 - a. For all breast implants: lifetime replacement warranty in case of shell rupture.
 - b. For breast implants with micropolyurethane-foam coating used for cosmetic breast augmentation: a maximum 10 years replacement guarantee from the implantation date in case of capsular contracture Baker grade III or IV
 - c. For breast implants with micropolyurethane-foam coating used for cosmetic breast augmentation: a maximum 10 years replacement guarantee from the implantation date in case of rotation / dislocation of the implant.
 - d. replacement guarantee means that the affected implant can be exchanged for a POLYTECH Health & Aesthetics implant of the same type, the size is free to choose. Replacement surgery costs are not covered. The payment of a sum of money instead of an exchange implant is not possible.
- Registration for the extended warranty program can be made at the earliest directly after the implantation surgery and at the latest up to 6 months thereafter.
- 4. Registration is only valid if all fields of the registration form are filled in completely and correctly. If you do not find the required information on your implant passport, please contact your surgeon and fill in the registration form together with him. POLYTECH Health & Aesthetics reserves the right to reject applications that are not readable or not filled out completely and correctly.
- 5. It is mandatory that you renew your participation annually. The renovation is done by responding to the invitation to participate in our Annual Survey, which you receive from POLYTECH Health & Aesthetics once a year via e-mail. The Annual Survey is initiated every year around April or May. We contact all patients registered until 30 March of the year before. You will receive your personal access data for the respective Annual Survey via e-mail. If you have not received your e-mail until the end of May and think that we may have left you out, please contact us via ioe@polytechhealth.com. Your replies are to be submitted via the response module "Annual Survey" on our website. If a survey remains without response, the extended warranty expires automatically at the end of the calendar year specified on the survey
- By registering for the program Implants of Excellence you accept these conditions of participation for the provision of our extended services at a total. Changes, additions or restrictions are not accepted by POLYTECH Health & Aesthetics.

form, which went unanswered.

- 7. POLYTECH Health & Aesthetics GmbH runs the extended warranty program Implants of Excellence voluntarily and reserves the right to cancel it at any time. Agreements and registrations which are made up to that time will not be affected by such a decision. The program is only valid in countries supplied by POLYTECH Health & Aesthetics. No claim can be asserted by parties from other countries.
- 8. Exclusions for the validity of the guarantee are as follows:
 - a. The replacement warranty in case of shell rupture does not apply in the following cases:
 - Damage to the implant prior to or during the implantation surgery
 - Damage to the implant due to an accident / injury
 - Damage to the implant during a mammogram
 - Damage to the implant during an open or closed capsulotomy
 - Damage to the implant during a surgical procedure
 - b. The exchange guarantee for implants with micropolyurethane-foam coating does not apply in the following cases:
 - The replacement guarantee does not apply to the indication of breast reconstruction.
 - The replacement guarantee does not apply for a capsular contracture Baker grade I or II.
 - The replacement guarantee applies only if the implant was placed in virgin tissue (no capsule or scar tissue).
 - The replacement guarantee applies only if postoperative wound healing was inconspicuous and occurred with cell integration into the micropolyurethane foam.
 - The replacement guarantee does not apply if complications like haematoma, seroma or infections related to the surgery occurred.
 - The capsular contracture Baker grade III or IV has to be documented photographically by the surgeon before the implant exchange.
 - The implant dislocation / rotation has to be documented photographically by the surgeon before the implant exchange.
- The implantation must be performed by a qualified surgeon, taking into account the POLYTECH Health & Aesthetics instructions for use of implants and using current surgical techniques.
 - The diagnosis of implant rupture (applicable to all implants), or (applicable only to implants coated with micropolyurethane foam) the diagnosis of capsular contracture Baker grade to III or IV, or of rotation / dislocation and the subsequent explantation have to be made by the same surgeon, who performed the initial implantation (alternatively diagnosis and surgery may be performed by the same clinic). If it is not possible to contact the surgeon who performed the initial implantation, another surgeon can be chosen in agreement with POLYTECH Health & Aesthetics. The same applies to clinics.
- 10. Each implant for which a replacement warranty claim is made, has to be sent to POLYTECH Health & Aesthetics for examination together with a comprehensive surgery report. This must be done immediately after implant removal, but no later than 4 weeks after the surgery. If no such delivery is made, POLYTECH Health & Aesthetics reserves the right not to grant the implant replacement.

POLYTECH Health & Aesthetics GmbH

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Implants made by POLYTECH – QUALITY made in Germany

