



Implants of Excellence

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

*Making an informed decision —
because there are differences.*

POLYTECH

Health & Aesthetics



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 CE-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.

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 footnotes page 12)
-  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 footnotes page 12)

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 can you benefit from the program Implants of Excellence?

Once you have had your implant surgery, please fill in your personal registration form (see p.13), fax it or put it in the enclosed envelope and send it to us. Or register online at www.polytech-health-aesthetics.com. You will then receive your personal registration card and further information on the program **Implants of Excellence**.

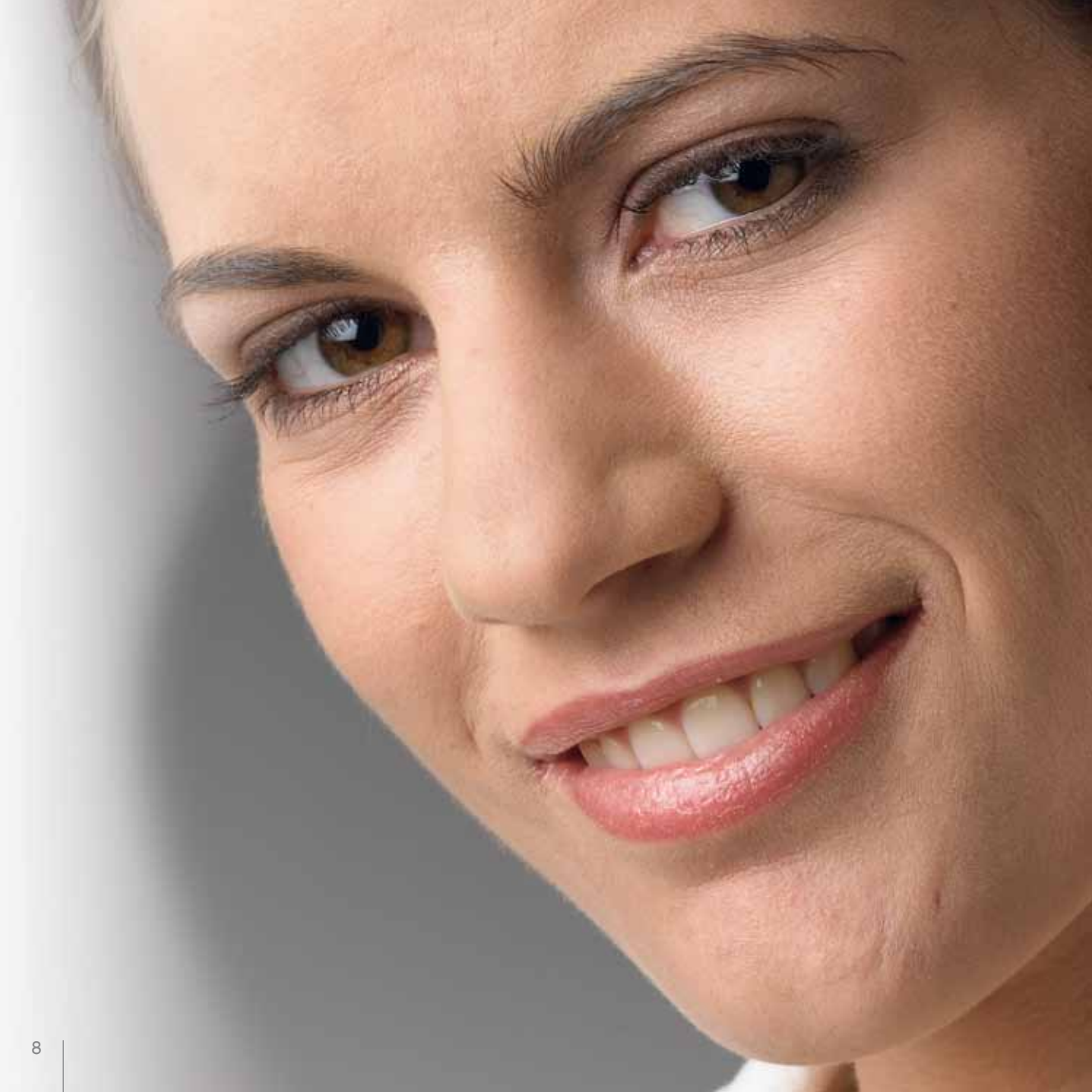
With **Implants of Excellence** we document the high product quality of our POLYTECH Health & Aesthetics silicone-gel-filled breast implants, and this documentation increases your safety.

Once a year, we will ask you to fill in an information leaflet and return it to us. This information leaflet will contain a few easy-to-answer questions about your satisfaction with the implant/s and your well-being. You return your personally completed information leaflet by air mail or fax, or give us your replies via the **Implants of Excellence** "Annual Information" online module on our website www.polytech-health-aesthetics.com. Then your **Implants of Excellence** warranty will be extended for another year within the defined period. Access data for the online module will be supplied in a letter accompanying the leaflet. Please be aware of the fact that the extended warranty program will only continue after our receipt of your completed annual leaflet or once we have received 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 delivering the answers to the questions submitted to you in the annual information leaflet. 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 footnotes page 12)

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 footnotes page 12)

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 footnotes page 12)

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.



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 (implantsofexcellence@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 and send the explanted implant and a detailed report to

POLYTECH Health & Aesthetics GmbH

Altheimer Strasse 32 | 64807 Dieburg | Germany

for an in-depth examination.

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).***

- * The guarantee does not cover exchange of a new silicone gel-filled breast implant in one of the following cases:
 - damage of the implant before or during implantation
 - damage of the implant due to trauma
 - damage of the implant during mammography
 - damage of the implant during an open or closed capsulotomy
 - damage of the implant caused by a surgical intervention

- ** The exchange guarantee for micropolyurethane-coated implants does not cover the indication breast reconstruction. The exchange guarantee does not cover a capsular contracture Baker grade I or II.
 - The exchange guarantee is only valid if the micropolyurethane-coated implant was placed in virgin tissue (no capsular or scar tissue).
 - The exchange guarantee is only valid if postoperative wound healing was inconspicuous with cell integration into the micropolyurethane foam.
 - The exchange guarantee is not valid if complications like haema-

toma, 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 rotation / dislocation has to be documented photographically by the surgeon before the implant exchange.

- *** If it is not possible to contact the surgeon who originally performed the implantation, another surgeon can be chosen in agreement with POLYTECH Health & Aesthetics GmbH; this also applies to the clinic.

POLYTECH Health & Aesthetics GmbH runs the extended warranty programme 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 programme is only valid in countries supplied by POLYTECH Health & Aesthetics. No claim can be asserted by parties from other countries.

For **online registration** please go to:
www.polytech-health-aesthetics.com
"Implants of Excellence" Online Registration

Registration for the programme Implants of Excellence

Please detach along the perforated line, fold twice
and send back using the enclosed envelope.

Name and address of the patient:

Family name, first name ↑

Street ↑

Postal code, city, country ↑

LEFT

RIGHT

Implant/s reference number/s REF ↑

LEFT

RIGHT

Implant/s serial number/s SN ↑

Implantation date ↑

eMail address (optional) ↑

Name and address of the surgeon who performed the implantation:

Clinic ↑

Name of surgeon ↑

Street ↑

Postal code, city, country ↑

Indication:

- Breast enlargement
- Reconstruction
- Implant exchange

Implant position:

- Above the breast muscle
- Below the breast muscle
- Other position:

Approach for the implantation:

- Below the breast
- Through the armpit
- Around the nipple
- Other approach:

Please send this registration form to:

POLYTECH Health & Aesthetics GmbH
Implants of Excellence
Altheimer Strasse 32
64807 Dieburg
Germany

If you have any questions, please do not hesitate to contact us:

Postal address: see above

Fax: 0049 (0)6071 9863-30

eMail: Implants.of.Excellence@PolytechHealth.com

(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.)

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:

Signature of the patient, date, place

Your personal registration card shall be send:

- to your home address
- to the address of your surgeon



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Quality made in Germany