



## International Society of Aesthetic Plastic Surgery

**Executive Office** 45 Lyme Road, Suite 304 – Hanover, New Hampshire 03755 USA  
t / 1-603-643-2325 f / 1-603-643-1444 e / [isaps@conmx.net](mailto:isaps@conmx.net) w / [www.isaps.org](http://www.isaps.org)

---

**ISAPS has two missions: ongoing education of our member surgeons and the safety of their patients.** In the following **Frequently Asked Questions** (FAQs), our Board of Directors provides patients who have breast implants with information about the ongoing PIP/ROFIL breast implant controversy.



### **1. What is wrong with the affected PIP/ROFIL implants?**

The French manufacturer Poly Implant Protheses (PIP) and the Dutch company Rofil Medical used inferior, industrial grade, silicone in the breast implants they produced and sold. These products have a higher rupture rate than other available implants. Rupture can cause inflammation from silicone leaking out into surrounding tissue.

### **2. Which implants are affected?**

Affected products are PIP breast implants that were used since 2001. These implants were also marketed under the name M-implant by the company Rofil Medical in the Netherlands and distributed in Germany by the company Rofil Medro. Affected Rofil implants are designated as IMGHC-TX, MX-IMGHC, and IMGHC-LS. There is strong suspicion that PIP and ROFIL implants that were manufactured before 2001 are also affected and are prone to a higher rupture rate and therefore silicone leakage.

### **3. How do I know what brand of implants I have?**

Typically, patients receive an implant ID card after such an operation which gives information about the implant, the size and the batch number. The surgeon's name and the date of implantation should also be recorded. If you do not have such a card, we recommend that you contact the surgeon who performed the procedure to check his records and tell you.

### **4. How high is the risk that the implant shell can rupture and for silicone to leak out?**

Recent studies by the French authorities determined a risk of rupture of up to 11.1% for PIP implants. In conventional implants, the rupture rate is up to 2%. The durability of the PIP/Rofil implants appears to be much lower than normally accepted standards.

### **5. What happens when silicone leaks from an implant?**

Cracks in the outer shell of the implant can allow silicone to leak out and enter the body. First, the silicone passes through the lymphatic system into the lymph nodes in the armpit. From there it can move into the internal organs, which is rare. This industrial grade silicone can cause severe inflammation, irritation, and in some cases effusion. On the basis of previous studies, no increased risk of cancer was shown.

### **6. Do I notice when an implant ruptures?**

Probably not because a crack in the implant shell can remain unnoticed, or it can lead to non-specific changes. Enlarged lymph nodes in the armpit should always be an alarm signal that leads the patient to consult with their doctor. After an accident or violent blow to the chest, you should see your doctor so he can decide if an ultrasound or magnetic resonance imaging (MRI) examination is appropriate. These tests will offer clues to determine if there is a rupture or leakage, but often provide false negative results - meaning that no silicone leaks are seen.

### **7. What should I do if I have a PIP or Rofil implant?**

Definitely go promptly to the surgeon who operated on you for a consultation. The International Society of Aesthetic Plastic Surgeons (ISAPS) strongly supports the recommendation of the French authorities to remove the implants as a precaution, even if no symptoms or hints of rupture or leakage are present. Of course, you can decide after consulting with your doctor not to have surgery and to return instead for regular checkups. If you decide not to have the implants removed, we recommend ultrasound or MRI scans twice each year to check for ruptures.

**8. Will my health insurance cover the surgery costs to remove or replace the implants?** As an international society with members in 93 countries we cannot provide an exact answer to this question. We advise you to check with your plastic surgeon and your health insurance provider.

### **9. If I have my implants removed, is it possible to put new implants in at the same time?**

If the implants are intact, it is always possible during the same procedure to replace them. If, however, there are complications because of the state of the implant, it may be that insertion of new implants in the same operation is not possible if rupture has been undetected for a longer period and if the industrial silicone has caused an inflammatory reaction in the surrounding tissue.

### **10. Do I need to look for a special surgeon?**

As the implant removal may be complicated, you should always look for a board certified plastic surgeon as he will have the experience to deal with unexpected problems. The forty-one year old International Society of Aesthetic Plastic Surgery is the largest international society of individual board certified aesthetic plastic surgeons with more than 2,100 members in 93 countries. Surgeons undergo a strict application process to determine their qualifications to join the society. You will find a list of ISAPS members in your country on our website [www.isaps.org](http://www.isaps.org)

---

#### **Dirk F. Richter, MD, PhD**

Chair - Patient Safety Committee  
Member, ISAPS Board of Directors  
Wesseling, Germany  
Email: [dr.dirk.richter@t-online.de](mailto:dr.dirk.richter@t-online.de)

---

#### **Joao C. Sampaio Goes, MD, PhD**

Chair - Communications Committee  
ISAPS Past President  
São Paulo, Brazil  
Email: [clinica@sampaio Goes.com](mailto:clinica@sampaio Goes.com)