

Defective "PIP" silicone-filled breast implants:

New information

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France is recommending, as a preventive measure, that PIP breast implants be surgically removed, despite the fact that scientific investigations have found no link between the PIP implants and cancer in some patients having received them. Other EU countries consider this measure as disproportionate, considering the findings to date and the risks that are inherent to any surgery. Swissmedic shares this opinion, but nevertheless asks all women with these implants to take into consideration the recommendations published on 8 June 2011.

The French agency AFSSAPS halted the marketing of breast implants from the French firm Poly Implants Prothèse (PIP) early in 2010 because poor-quality, unreliable filling material was used. These implants were also withdrawn from the Swiss market in April 2010 (see the following announcement available in German and French):

<http://www.swissmedic.ch/aktuell/00003/01247/index.html?lang=de>

Based on investigations carried out by the French agency AFSSAPS and the English regulatory authority MHRA, Swissmedic has constantly kept the public informed regarding possible risks related to these products. Recommendations were drawn up for women with these implants in co-ordination with the Swiss Society for Plastic, Reconstructive and Aesthetic Surgery (SGPRAC) and the Swiss Society for Senology, (SGS/SSS), and were published on 8 June 2011.

Based on current reports from France concerning the possibility of a link between cancer and breast implants from the firm PIP, the risks inherent to this product were again examined. The evaluation is being carried out in parallel in several EU countries: in some of them, several tens of thousands of women have received the said implants. The results of the evaluation are being exchanged by a transnational network of health ministries and the agencies responsible for the control of medical devices. Swissmedic is also a part of this network.

Experience to date has revealed reporting rates of adverse events (e.g. the implants tearing or inflammation of the surrounding tissues) that vary considerably. The figures are between less than 1% and 5%.

France has today announced that all women with PIP implants are not at any greater risk of cancer in comparison with other implants. Nevertheless, and given the high rate of adverse events in France (around 5%), a recommendation has been issued for the implants to be removed as a preventive measure. England, which is the EU country with the highest number of patients concerned (over 80,000 implants), considers this measure to be disproportionate, since the possible risks of surgery – which may not be necessary – should also be taken into consideration. The rate of adverse incidents related to implants in England is moreover relatively low, at around 1%. Based on available data, other countries concerned also do not currently recommend the removal of the implants.

In Switzerland, around 280 women have received PIP implants. The adverse event rate is less than 1%. These low figures do not permit a risk assessment based on Swiss data alone. Given the information available today, Swissmedic also considers that a general recommendation to have all PIP implants surgically removed to be disproportionate, bearing in mind the potential risks of the surgery involved. This is also based on the fact that scientific investigations of the filling material to date have revealed no evidence of carcinogenic or toxic effects.

Swissmedic nevertheless refers to the recommendations already published in June, which should be taken into consideration until further notice. If new findings emerge, Swissmedic will issue information once again, in co-ordination with the other EU countries.

Recommendations

In view of the current status of information, women with silicone gel breast implants from the firm "PIP" are recommended to consult their doctor (surgeon) for a check every six months. In the case of pain or any changes to the breast area or armpits, women concerned should have a medical examination without delay.

The removal of intact implants may be simpler than removing them as a result of tears or in the case of inflammation. Therefore, during the checks, women can also discuss the possibility of removing or replacing the implants before the filling material leaks, and without signs of inflammation. The risks and benefits should be considered on a case to case basis.

Should filling material leak out of an implant pouch, or if there is any sign of inflammation in the breast area or the armpits, the expert societies recommend the removal of both implants.

Register for breast implants

All women with silicone-filled "PIP" implants can, with immediate effect, be included via their doctor (surgeon) in the register for breast implants created by the Swiss Society for Plastic, Reconstructive and Aesthetic surgery (SGPRAC). This register makes it possible to monitor patients and to issue reminders for the six-monthly checks.

The register is maintained and evaluated by the SGPRAC, but is also available to other physicians. All members of the SGPRAC are physicians. The register is not used for marketing purposes, and names and addresses are not released to third parties.

Links to further and additional information: [Publication of 8 June 2011](#)