

New information about a case of breast cancer (adenocarcinoma) in a woman using prefilled, silicone gel PIP breast implants

Please also read:

- *Surgeons information letter*
- *Questions and answers for women with PIP breast implants*

Breast cancer

The malignant tumours that develop in the mammary epithelium are the most common type of cancer in women in France. They affect approximately 50,000 women every year. Two-thirds of these cases occur after age 50.

On 5 December 2011, Afssaps received a report of a case of breast cancer (adenocarcinoma) in a patient who had been using PIP implants for several years.

The risk of breast cancer in women with breast implants

The FDA recently (June 2011) assessed the occurrence of breast cancer in women with silicone breast implants. After an extensive review of cases in the U.S. and of the literature, it concluded that breast implants were safe and stated that women with this type of implants presented no increased risk of developing breast cancer.

We note that in January 2011, the FDA also reported a “possible” association of a very rare form of lymphoma (anaplastic, large-cell lymphoma) with breast implants (see the 30 November news update) while emphasizing that the extremely low rate of occurrence of this type of lymphoma and the data collected to date on breast implants did not call into question the safety of these devices.

Defective PIP breast implants

The first aberrations observed clinically and reported under medical device vigilance showed, in late 2009, an increase in the number of ruptures in these breast implants, resulting in a higher rupture rate than for the implants of other manufacturers. An abnormal seepage of the gel was also reported.

The inspection and verifications conducted by Afssaps resulted in reports of several non-compliances, thus justifying suspension of the sale of these implants on 29 March 2010. Those defects concerned:

- The type of silicone gel used inside the implants: the gel in question was not the proper quality of silicone gel for use in breast implants;
- The mechanical strength of the implants: the stretching to rupture test was non-compliant. This result showed that the envelopes filled with PIP gel were fragile, and corroborated the findings of retrospective medical device vigilance studies conducted by Afssaps at several centres that use these implants, which showed a rupture rate higher than the average;
The “irritant potential” of the silicone gel used, which is not found in the silicone gels used in other implants, nor in the gel declared in the authorisation for marketing file. This may cause inflammatory reactions in some patients;
- In the tests performed, this gel was not found to have any abnormal gene toxicity. That does not exclude, especially given its irritant potential, the fact that this gel might have toxic effects in the long term.

The risks of cancer with PIP implants

To date, two cases have been reported to Afssaps: one concerns a case of anaplastic, large-cell lymphoma, and the other, a case of breast adenocarcinoma. This new information justified upgrading the recommendations Afssaps has issued for women and healthcare professionals.

Afssaps recommendations

- Patients who have PIP implants must check with their physician or surgeon and systematically be offered a clinical exam and suitable radiological examinations.
- Any rupture, suspected rupture or seepage of an implant must result in it being removed, along with the second implant.
- Patients should discuss with their surgeon the possibility of preventive removal of their implant, even if there is no clinical sign of its deterioration.

Given these new cases, the Ministry of Health has contacted the competent healthcare agencies and learned societies in order to develop specific recommendations for healthcare professionals, to be released within the month, on methods of diagnosis, removal and monitoring.

Xavier Bertrand, the Minister of Labour, Employment and Health, and Nora Berra, State Secretary for Public Health, have requested that the General Director of Public Health set up a monitoring committee comprised of all stakeholders (health authorities, healthcare professionals, learned societies, patients' associations, etc.).

Afssaps wishes to remind healthcare professionals of the importance of reporting under medical device vigilance any adverse event observed with these devices, and specifically any case of lymphoma or breast cancer, as well as any preventive removals.

The conditions for reimbursement by the national health plan are as follows:

- All women with PIP implants will have their medical expenses reimbursed for any procedures related to removal of their implant(s) (ultrasound exams, lab tests, removal of the implant, post-operative check-ups).
- Women who have had reconstructive surgery after a case of breast cancer will also be reimbursed for the insertion of a new implant.

All required information is available on the National Health Plan (Assurance Maladie) Web site: <http://www.ameli.fr/assures/soins-et-remboursements/combien-serez-vous-rembourse/implants-mammaires.php>