

News Update on PIP Breast Implants

Hot-line for answers to questions from the general public:

0800 636 636

(Open Monday – Saturday, 9 a.m. – 7 p.m.)

1. **What is a lymphoma?**
2. **Is there a link between the risk of lymphoma and the use of breast implants?**
3. **Does implanting breast implants filled with PIP gel increase the risk of having breast lymphoma?**
4. **Does implanting breast implants of any other type increase the risk of having breast lymphoma?**
5. **What is breast cancer?**
6. **What can be said about the recently reported case of breast cancer?**
7. **Does that affect the recommendations for monitoring given to women with PIP implants?**
8. **What are the reimbursement procedures for the examinations and surgery related to the use of PIP gel implants?**

1. **What is a lymphoma?**

A lymphoma is a malignant tumour in the lymphatic system. The lymphatic system is part of our body's defences. A lymphoma may appear in various parts of the body, such as lymph nodes, but also in our skin, bones, brain and many anatomical locations, including the breasts. Anaplastic, large-cell lymphoma is a very rare form of lymphoma: according to U.S. cancer records (SEER), it is estimated that one woman in 500,000 gets this type of lymphoma every year in the United States. This form of lymphoma occurs even more rarely in the breast, and in the U.S. the rate is estimated to be 3 cases per year for every 100 million women.

2. **Is there a link between the risk of lymphoma and the use of breast implants?**

In January 2011, the U.S. FDA found that, worldwide, there were 60 documented cases of anaplastic, large-cell lymphoma associated with breast implants, 34 of which were in the breast (17 in the United States). Given that nearly 4 million women received breast implants in the U.S. between 1998 and 2009, the FDA estimates that the rate of anaplastic, large-cell lymphomas found in women with breast implants was higher than the estimated rate based on epidemiological data for the overall population of the United States.

3. **Does implanting breast implants filled with PIP gel increase the risk of having breast lymphoma?**

To date, Afssaps has had no knowledge of reports of any lymphoma occurring in a patient using a PIP breast

implant in France. The results of tests conducted on PIP implants have not shown any gene toxic effect (effect on cell DNA) of the filling gel. However, this gel was found to have an irritant effect not found with the silicone gels in other implants and that may induce inflammatory reactions in some patients. The case reported in France in itself constitutes an item to be taken into consideration at the epidemiological level since it occurred in one woman among the 30,000 women using the PIP implants that have been taken off the market.

4. Does implanting breast implants of any other type increase the risk of having breast lymphoma?

In January 2011, the FDA concluded that it is currently not possible to reliably link this type of lymphoma to a certain type of implant, specifying that the physiological and pathological cause of this serious event has not yet been determined and concluding that, in light of the extremely low rate of occurrence of this type of lymphoma, and of the data collected to date on breast implants, the safety of these devices is not being called into question.

5. What is breast cancer?

Breast cancer consists of a malignant tumour of the mammary gland. Breast cancer is the most common type of cancer in women, with approximately 50,000 new cases per year. The most frequent type of breast cancer is adenocarcinomas (95%). Two-thirds of the cases of breast cancer occur after age 50.

6. What can be said about the recently reported case of breast cancer?

Breast cancer may appear in all women who use implants. Given the aberrations in the PIP implants, special precautions should be taken for women who have this type of implant.

7. Does that affect the recommendations for monitoring given to women with PIP implants?

This new information has led Afssaps to upgrade its recommendations to all healthcare professionals so that it can be prepared to deal with each individual case, both for women and for healthcare professionals:

- Patients who have PIP implants must 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.

In addition, 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.).

8. What are the reimbursement procedures for the examinations and surgery related to the wearing of PIP gel prosthesis?

As a result of Afssaps recommendations, 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>