

Information for women with PIP breast implants

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1 Which breast implants are involved with the decision?

The breast implants concerned are implants pre-filled with silicone gel manufactured by the company Poly Implant Prothèse (PIP). Afssaps decided to suspend the marketing and use of such breast implants as well as to withdraw the products from the market. Indeed, this company uses for its silicone pre-filled breast implants a gel different from the one it declared at the time of the marketing authorisation.

2 What is the problem with these implants ?

Afssaps decided to carry out an inspection on the premises of PIP Company after vigilance reports revealed an increase in the number of declaration of implant ruptures. The elements collected during this inspection showed that the implants were filled with a silicone gel different from the one the company had declared at the time of marketing. Therefore, these implants do not comply with current regulations and have not been subjected to the required evaluations. Controls on this gel are currently being carried out by Afssaps. The results of these controls will be published as soon as they are available.

3 How can I find out if my implant is involved?

Information about the type of breast implant inserted is available in the handbook (operative record, implant card) provided by the surgeon after your operation. In case you don't have this information, we recommend you contact the surgeon who operated on you.

4 What if I cannot find the address of the surgeon who performed my surgical operation?

The health-care facility where you were treated has this information. It will be easier to find your medical records if you can provide information such as date of surgery, name of surgeon..etc..

5 What should I do if I have one of these implants?

You should make an appointment with your doctor or surgeon in order to be examined so that he/she can prescribe an appropriate examination if necessary.

We remind you that in any case, a follow-up is set up for all women with breast implants

6 What are the risks for my health?

At this point no complications different from those usually encountered with other breast implants have been identified.

However, a higher frequency of rupture of these implants and local inflammatory reactions have been observed.

7 Are these risks potentially serious?

No, but a ruptured breast implant should be replaced. This recommendation applies to any type of breast implant

8 What are the symptoms of an implant rupture?

Most of the time implants rupture without any symptom. An implant rupture can be detected during a clinical examination. The health professional will prescribe additional examinations if necessary. For this reason it is important to regularly keep up with your follow-ups .

9 Should I have my breast implants removed?

To date, according to experts, nothing justifies a preventive replacement of the implant under which the surgery may be considered.

10 If they are removed, can they be replaced?!

Usually, the insertion of new implants is possible. Your surgeon will explain the conditions

11 Who should I contact to get further information?

First, you should contact your surgeon or your doctor. A free number (0800 636 636) has also been set up at Afssaps.

12 What long-term medical follow-up should I have?

You must follow the usual recommended follow-up and have an ultrasound performed every year.

13 According to Afssaps what should be done with the removed implants?

What should be done with removed implants is up to the patient. Laboratory controls currently in progress do not require the gathering of removed implants. They are performed on prostheses taken from different stocks.

14 What kind of tests are performed on the PIP company implants and when will the results be disclosed ?

Three types of analyses are being performed on the PIP implants:

- characterisation of different silicone gel used,
- evaluation of implants properties as well as used gel properties in order to characterise the implants resistance and particularly the shell resistance.
- compatibility with biological tissue tests in order to evaluate the risk of middle and long term side effects occurrence.

The latter results won't be available before the end of August. A global analysis of the results of all these tests is necessary to re-assess the recommendations to patients with PIP implants. This analysis is expected to be delivered by mid- September.

In the meantime, no element justifies modifying the answers to questions 7,9 and 11.

15 How are complications following the rupture of a PIP implant covered?

Regarding the coverage of complications due to silicone gel leakage from a breast implant, Social Security indicates that if it has not covered the initial breast implant surgery (in the case of aesthetic surgery), it will only cover, the medical examination needed for the diagnosis of gel leakage, the implant removal, the hospitalisation costs as well as the post-operative care, directly related to the ablation procedure
You'll find more information on the Health Insurance website

<http://www.ameli.fr/assures/soins-et-remboursements/combien-serez-vous-rembourse/implants-mammaires.php>

16 Should health-care facilities destroy the PIP implants still in stock?

Afssaps has not requested the destruction of these products. However, the terms of the decision imply the products should not be used as long as the suspension decision is in effect. Neither the scheduled analyses nor the legal procedure in progress require that the products currently in stock in the implantation facilities be kept.

17 Have other EU member States carried out a recall of PIP implants?

The European Commission has been informed by France and strongly advises the competent authorities of other EU Member States, warned by Afssaps, to take all useful and necessary measures in order to verify the involved implants are no longer marketed, distributed, put into service or exported.