

Saint-Denis, 23 December 2011

Letter to healthcare professionals

Medical devices vigilance

Important information on the monitoring of women who have breast implants prefilled with PIP silicone gel

Dear Sir or Madam,

On 29 March 2010, Afssaps suspended the market access, distribution, exportation and use of the breast implants prefilled with silicone gel manufactured by the Poly Implant Prothese company (PIP).

On 7 December, ministry officials in charge of public health called on public health agencies (the National Cancer Institute, the Health Emergencies Agency and Afssaps) to seek their expert advice, along with learned societies, on reports of adverse events in women with PIP breast implants.

The opinion rendered on 22 December indicates that at present there is no increased risk of cancer in women with PIP-brand breast implants compared to those with other implants. However, the proven risks associated with these implants are ruptures and irritation caused by the gel, which may lead to inflammation and make their removal difficult.

Health ministry officials have thus decided:

1. To reinforce the recommendations issued by Afssaps:
 - Women with breast implants should check the brand of their implant(s) on the care they were given. If they have no card, they should contact their surgeon or, if that is not possible, the institution where the surgery was performed.
 - Patients with PIP implants should consult with their surgeon. At that time, it will be proposed that they have a preventive removal, even in the absence of clinical symptoms of deterioration of the implant. If they decide against removal, they should have the benefit of monitoring by breast and underarm echography exams every 6 months.
 - Any rupture, suspected rupture or oozing of an implant should result in its removal, along with that of the second implant (if any).
 - Before any removal, for whatever reason, an imaging work-up (including a mammography and breast and underarm echography) done recently should be available.
2. To adopt structural measures enabling any woman who wishes to opt for preventive removal to do so. Ministry officials have therefore requested that Regional Health Agencies (RHA) set up, starting in early January, a hot-line intended for patients with PIP breast implants who have difficulty gaining access to a healthcare professional, in order to offer them a list of institutions where they may receive care.
3. To set up a prospective epidemiological study on implant ruptures.

Afssaps would also like to remind you of the obligation to report to the medical device safety department, by e-mail at: dedim.ugsv@afssaps.sante.fr, or by fax at: 01.55.87.37.02, any adverse event observed with these devices.

All of the data and documents related to this matter, and in particular the updated answers to the most frequently asked questions, are available on the Afssaps Web site.

For any additional information, a national Green Number (0800 636 636) is available. It is open Monday-Saturday, from 9 a.m. to 7 p.m.

Yours sincerely,

Prof. Dominique Maraninchi
Afssaps Director General