



PRESS RELEASE

Paris, 23 December 2011

Update of Recommendations for Women with Silicone filled Poly Implant Prosthesis (PIP) Breast Implants

Xavier Bertrand, Minister for Labour, Employment and Health, and Nora Berra, State Secretary for Public Health, are updating the healthcare recommendations for women with PIP implants.

As a preventive measure, but not as an emergency, they suggest that the explantation of the implants, even without any clinical signs of deterioration of the implant, should be proposed to women with PIP implants. This procedure should be discussed during a visit to their surgeon, already recommended as a preliminary step.

On December the 7th, the ministry officials responsible for public health asked government health oversight agencies (the National Cancer Institute, the Public Health Monitoring Institute and Afssaps) to obtain their expert input, along with professional societies, on reports of adverse effects in women with PIP implants.

The opinion issued on 22 December indicates that to date there is no increased risk of cancer in women who have PIP implants compared to other implants. However, the well-documented risks associated with these implants are ruptures and the gel's capacity to cause irritation that may lead to inflammatory reactions, thus making removal difficult.

The ministry officials responsible for public health have therefore decided:

1. To reinforce the recommendations made by Afssaps:
 - Women with breast implants shall check the brand of their implant on the implant card they were given. If they have no such card, they shall contact their surgeon or the institution where the implantation was done.
 - Patients with PIP implants shall consult their surgeon. At that time, they will be proposed a preventive explantation, even if there is no clinical sign of deterioration of the implant. If they do not wish to have their implant removed, they shall receive a follow up by ultrasound scan every 6 months, targeting breast and axillaries lymph node areas;
 - Any rupture, suspected rupture or oozing of an implant shall result in its explantation, as well as the second breast implant.
 - Prior to any removal, whatever the reason is, a recent imaging (including a mammography and a breast and axillary ultrasound scan) shall be available.

2. To ensure that any woman who wishes to undertake preventive explantation can do so, the ministry officials have requested that all Regional Public Health Agencies (ARS) set up, as of early January, a hotline for women with PIP breast implants who might have difficulties reaching a healthcare professional to propose them a list of institutions able to treat them.
3. To initiate a prospective epidemiological study on ruptured breast implants.

The involved healthcare institutions and healthcare professionals are likewise being informed of this decision and these new recommendations.

Any costs associated with eventual explantation, including hospitalisation, will be covered by the national health plan. In the case of women who have had reconstructive surgery following a breast cancer, the implantation of a new prosthesis will also be covered by the health plan. Ministry officials remind that independent plastic surgeons are requested not to charge off-schedule fees for these procedures, as recommended by the French Medical Association.

The monitoring committee, which will meet at the Ministry of Health on January the 5th 2012, will provide another progress report on the situation and will closely examine the procedures and measures for applying this decision in order to best respond to the concerns of the women involved, and to enhance the management of all requests for explantation.

For any additional information, a free hotline : 0800 636 636, is available nationwide, from Monday through Saturday: 9:00 a.m. – 7:00 p.m.

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