afssaps
Agence française de sécurité sanitaire
des produits de santé

REPUBLIQUE FRANÇAISE

MEDICAL DEVICES
EVALUATION DIRECTION

VIGILANCE DEPARTEMENT

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Silicone based filling gel breast implants from Poly Implant Prothèse Company : update of tests results

History

On March 29th, 2010, Afssaps suspended the marketing and use of breast implants pre-filled with silicone based gel manufactured by Poly Implant Prothèse Company (PIP).
This decision followed both the observation made in 2009 of an increase in precocious shell ruptures of the breast implants and the findings of the inspection conducted by Afssaps in the premises of this company following this vigilance observation. This inspection, conducted in March 2010, had highlighted the use by Poly Implant Prothèse of a filling gel different from the one declared in the design file and the manufacturing file of these implants and not dedicated to medical use.

A first series of tests on the PIP's implants had especially showed:

- A significant heterogeneity in the quality of these implants, so they do not all have the same level of fragility;
- An irritant behaviour of PIP's gel that is not found with other silicone gels of other breast implants nor with the one tested for the placing on the market;
- Results which do not allow to conclude about a possible genotoxic effect (negative results for both in vitro tests and non conclusive results for the in vivo test, "mouse micronucleus assay").

These results led Afssaps to issue on September 28, 2010, recommendations for women with PIP's implants and to initiate further testing to conclude about the genotoxicity of the gel.

Additional tests

The micronucleus test was performed again on mice, by optimizing the experimental conditions in order to approach the conditions of implantation of these prostheses. It was supplemented by another in vivo test, also done on mice, the "comet assay". These two additional tests revealed no alteration in the DNA of mouse cells.

Therefore, the results of these tests do not show genotoxic effect of PIP's gel.

Vigilance data

Incidents reported under French materiovigilance system after the decision on March 2010 and supplemented by retrospective surveys conducted by Afssaps from several users of these prostheses have confirmed the heterogeneity of the quality of these prostheses. Indeed, highly variable rupture rate up to 10% and that, since the first years of implantation, have been noted among women reviewed by their physician following the recommendations of the Agency. Moreover, the phenomenon of leakage of the gel through the shell was confirmed with a rate up to 11%.

In case of rupture or leakage, storage of gel in axillaries lymph nodes (adenomegaly) can cause pain and / or inflammation. Even in the absence of clinical signs, the invasion of lymph nodes can be detected by palpation and / or ultrasound scan. Their removal may be considered in case of very disabling symptoms (pain, functional impairment). It must not be systematic taking into account risks of potential complications that may result ("big arm", sensitivity disorder).

Afssaps recommendations

In the absence of observed genotoxic effect, Afssaps maintains and updates its recommendations given in September 2010 :

1. For women with PIP's gel implants, AFSSAPS recommends:

- A clinical examination and an ultrasound scan every 6 months, targeting for each of these exams, breasts and axillaries lymph node areas.
- That any rupture, suspected rupture or leakage of prosthesis should lead to its explantation, as well as that of the second prosthesis.

Afssaps reminds that contact with the surgeon is an opportunity to discuss a possible explantation without clinical signs of deterioration of the prosthesis: the concerned women will consider the most appropriate attitude according to their personal situation, their feelings, the age of their prostheses and their expectations at the aesthetic level. This choice will take place after evaluation by the surgeon of the individual risk / benefit ratio, based on a preoperative assessment that takes into account medical history, surgical and anaesthetic risks, and the risk of complications inherent in the surgery. To make this discussion easier, a guideline to help the decision is available on the Afssaps website (link).

In addition it is recommended at the time of explantation of a prosthesis showing unusual signs of inflammation, to take a histological and immunohistochemical sample on the capsular contracture.

2. For women who turn to explantation of their PIP's implants, Afssaps doesn't recommend any specific follow-up.

However, if the implant was broken or showed signs of leakage of the gel, these elements must be recorded in the medical file of the patient to be taken into account in any subsequent clinical examination. Indeed, taking into account that gel can built up in the lymph nods over time, even after explantation achieved, any increase in the lymph nodes must be connected to the presence of PIP's gel.

Finally, in case of re implantation of new implants, Afssaps reminds that a yearly clinical follow-up is recommended.

All documents relating to this matter and in particular the answers to the most frequently asked questions are available on the Afssaps website http://www.afssaps.fr/.