# Proposed measures to be taken for women with PIP breast implants: Experts' opinion

*Coordinated by the National Cancer Institute (INCA)*

22 December 2011

22/12/2011

**Proposed Measures to be Taken for Women with PIP Breast Implants**

**Substantiated Opinion of the Group of Experts**

1. **In terms of the risk of cancer:**

- For large-cell anaplastic lymphomas:

Large-cell anaplastic lymphoma is an extremely rare disease.

The group acknowledges, based on the available data, that there could be an elevated risk in women with breast implants, regardless of the brand and contents of the implant (saline solution or silicone gel).

There is currently no data proving that there is a higher than normal risk of large-cell anaplastic lymphomas specific to PIP implants in comparison with other implants.

- For breast cancer (adenocarcinomas):

Breast cancer is a common disease.

The group acknowledges that currently available data support the conclusion that there is no elevated risk of breast adenocarcinoma in women with implants in comparison with the general population.

There is currently no data proving that there is a higher than normal risk of breast adenocarcinoma specific to PIP implants in comparison with other implants.

2. **Opinion on the decision to have the implant removed**

The task force acknowledges that the factors justifying implant removal are the presence of clinical and/or radiological signs suggesting a change in the implant and/or a request by the patient.

There are, at present, no grounds to justify emergency removal.

In asymptomatic women (no clinical and/or radiological evidence), the risks associated with not performing removal for preventive purposes are: a risk of rupture, a risk of falsely reassuring imagery (false negatives), a risk of a more complicated renewed surgery (aesthetic harm, increased risk of post-operatory complications), and the potential toxicity - currently poorly ascertained, of this non-compliant gel in PIP implants.

The risks associated with implant removal are: the risk associated with renewed surgery (anaesthesia and procedural) and the risk of a different morphological outcome.

The group wishes to stress that, in the absence of a demonstrated higher risk of cancer in women with PIP breast implants compared to other implants, its opinion on removal is based on the risks of rupture of the implant and those related to the non-compliance of the gel.

Given the lack of any new evidence concerning the non-compliant gel, and of new clinical data on specific complications, the experts deem that they do not have enough evidence to recommend systematic removal of these implants for purposes of prevention. However, they wish to reiterate the risk of premature rupture and the uncertainty concerning complications related to the irritant nature of this gel.

The group of experts notes that a prospective epidemiological study must be instituted on implant ruptures with records kept of clinical, radiological and histopathological data.

**3. Monitoring of women with PIP breast implants**

- **In the absence of any symptoms:**

In terms of the risk of breast cancer, there is no reason to change for women with breast implants the currently recommended procedures of screening and monitoring for this disease.

Given the increased risk of rupture of PIP implants, the group would maintain the monitoring measures recommended by Afssaps, that is *"a clinical exam and an echography every 6 months, targeting the breasts and underarm lymph node areas in both of these exams."*

The group maintains that a breast MRI is not indicated as a first-line procedure.

- **In the event of abnormal clinical and/or radiological symptoms:**

Consultation with a specialist is recommended before any treatment or procedure is authorised.

**4. Procedures to be followed in the event of implant removal**

Before any implant removal, on whatever grounds, an image work-up (including a mammography and breast and underarm echography) done recently should be available.

In all cases of implant removal:

- If there is abnormal periprosthetic fluid present (abnormal in appearance or amount), the liquid must be aspirated for cytological analysis.
- A biopsy must be done systematically on the capsule and periprosthetic tissue.

The largest possible capsulectomy should be performed whenever reasonably feasible, at the surgeon's discretion. The group recommends systematic histological analysis of the pieces of the capsulectomy.

In the event of an abnormality in the armpit, a histological or cytological analysis should be done. The group notes that curettage of the armpit is not indicated.

The biopsies and pieces from the operation should be preserved in formaldehyde to allow for additional investigations.

In the event of a suspected periprosthetic lesion, the samples collected should be frozen. In the event of a diagnosed or suspected case of lymphoma after anatomical and cytopathological analysis, samples must be sent to the Lymphopath network.

Immediate replacement with a new implant is foreseeable if the local conditions so permit. Otherwise, it could be proposed for some time after the removal. This should be discussed with the patient before undertaking any surgical procedure.

**5. Monitoring after removal**

In the case of implant removal, there is no special monitoring recommended given the absence of proof of an elevated risk of cancer associated with PIP implants.

The normal recommendations for breast cancer screening or monitoring apply, depending on the woman's risk factors and regardless of her history of implants.

*This opinion must be distributed in its entirety, without any additions or changes.*

**APPENDICES**

1. Letters requesting official action

2. Methodology used

3. List of the experts involved

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**REPUBLIC OF FRANCE**

Ministry of Labour, Employment and Health

Paris, 5 December 2011

**State Secretariat for Public Health**

**Ministry of Health**
Subdivision for policy on health practices and products
Office of Medical Devices and Other Health Products

DGS/PP3/

**MEMORANDUM**

**To: The President of the National Cancer Institute**

**Re: Constitution of a task force on the measures to be taken by healthcare professionals for women with breast implants from the Poly Implant Prothèse (PIP) company**

**REF.:** DGS/AFSSAPS/INCA Meeting on 2 December 2011

Following the death of a woman with a breast implant from the Poly Implant Prothese (PIP) company due to a lymphoma, I would be grateful if you could please set up a task force of healthcare professionals, specifically oncologists, haematologists and surgeons who do breast reconstructions following cancer surgery in order to determine the various measures to be taken by healthcare professionals related to:

- The implementation of monitoring of women with these implants, especially the value of performing MRI's or any other type of test;
- The surgical removal of PIP breast implants, specifically the performance of biopsies in healthy and affected areas: the procedures for collecting, preserving (especially freezing) and forwarding these samples to members of the Lymphopath network;
- The establishment of monitoring for women who have had these implants removed;
- The option of receive a new implant for patients who have already undergone removal;

distinguishing between women who have had cancer and those who have not.

I would also like to remind you that INCA will analyse the data in the Lymphopath data base and will report to us within 8 days the frequency of cases of anaplastic lymphomas in women, their locations and their potential association with the insertion of breast implants.

I would very much appreciate your sending me the above-mentioned information by 20 December 2011.

***Director General for Public Health***
***[signature]***
***Dr Jean-Yves Grall***

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REPUBLIC OF FRANCE

MINISTRY OF LABOUR, EMPLOYMENT AND HEALTH

Our Ref. No.: cab/CR/

Paris, 7 December 2011

**Re: Supplementary official request concerning measures to be taken by healthcare professionals concerning women with breast implants from the Poly Implant Prothese (PIP) company**

Following the death of a woman with a PIP breast implant due to a lymphoma, you were asked by the Director General for Public Health (see attachment) to constitute a task force of healthcare professionals, specifically oncologists, haematologists and surgeons who do breast reconstructions following cancer surgery in order to determine the various measures to be taken by healthcare professionals.

A second case of a serious adverse event in a woman with a PIP implant has been reported to Afssaps involving an adenocarcinoma in the breast with the implant.

In this context, in addition to the above-mentioned official request, I must request that the recommendations to be made by the task force for which you are responsible take this new item into account by also suggesting measures to be taken in cases where an adenocarcinoma is found.

I would very much appreciate your submitting all of the information requested in the original request of 5 December, supplemented by the present, by 20 December 2011.

**[signature]**

**Xavier Bertrand**

**Mrs Agnes Buzyn**
President of the National Cancer Institute
52, avenue André Morizet
92513 Boulogne-Billancourt

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**REPUBLIC OF FRANCE**

Ministry of Labour, Employment and Health

Paris, 19 December 2011

**State Secretariat for Public Health**

**Ministry of Health**
Subdivision for policy on health practices and products
Office of Medical Devices and Other Health Products

DGS/PP3/

# MEMORANDUM

To: The President of the National Cancer Institute

Re: Constitution of a task force on the measures to be taken by healthcare professionals for women with breast implants from the Poly Implant Prothese (PIP) company

REF.: - DGS/PP3 Memo of 5 December 2011, INCA Memo of 9 December 2011;
- DGS/AFSSAPS/INCA Meeting on 2 December 2011 and Meeting of the Committee for Women with PIP Breast Implants on 14 December 2011.

Following the death due to a lymphoma of a woman with a breast implant from the Poly Implant Prothese (PIP) company, I asked you in a memo on 5 December 2011 to constitute a task force of healthcare professionals, specifically oncologists, haematologists and surgeons who do breast reconstruction after cancer surgery in order to determine the various measures to be taken by healthcare professionals and especially concerning the implementation of monitoring of women with these implants.

As we discussed jointly, I wish to note that when this monitoring is set up, the indications for implant removal should be discussed.

In addition, as a follow-up to the questions raised during the meeting of the Monitoring Committee for Women with PIP Breast Implants on 14 December 2011, I am hereby requesting that you please inform me no later than 23 December 2011 if the removal of PIP breast implants should be systematic, even if there is no evidence of rupture or oozing of the implant, and how soon said removal should be done, taking into account the operatory and post-operatory risks of any eventual removals compared to the potential benefits expected related to monitoring or treatment.

*Dr Jean-Yves Grall*

*[signature]*

Director General for Public Health

# Appendix 2: Methodology

On 5 December 2011, the National Cancer Institute was asked by the Minister of Labour, Employment and Health to constitute a task force to formulate proposed measures to be taken for women with PIP breast implants containing silicone gel.

To that end, INCA set up a group of experts on 22 December 2011, which it asked to produce a medical and scientific opinion based on the risks of cancer and the data currently in its possession.

The group of experts was made up based on the principle of multi-disciplinarity and impartiality. The experts were named on an individual basis by request from the INCA or the suggestion of the respective learned societies (SFSPM, SOFMIS, SFP, SoFCPRE, SFH*) and by the Lymphopath network. The request was to include haematologists, oncologists, breast and plastic surgeons, radiologists, anatomic pathologists and public health physicians.

INCA chaired the discussions in order to obtain the opinions of the assembled experts on each issue. Those discussions served to identify consensual proposals within the group. Plans included the publication of any eventual divergent opinions.

The proposals were rewritten based on the expertise of the group. The reader should note that they thus are not based on the methodological premises of a "recommendation for clinical practice" RCP (method), which specifically requires an exhaustive analysis of the data in the literature, and they should thus not be considered as such.

All of the experts submitted public statements of disclosure, and these were analysed in light of the PIP implants problem in order to avoid any potential conflicts of interest.

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**SFSPM**: French Association of Senology and Breast Pathology
**SOFMIS**: French Association for Mastology and Breast Imaging
**SFP**: French Pathology Association
**SoFCPRE**: French Association of Reconstructive and Aesthetic Plastic Surgery
**SFH**: French Association of Haematology

**Appendix 3: List of Experts in the Group Organised by the National Cancer Institute**

- Thierry Molina, Anatomic Pathologist
- Nicole Brousse, Anatomic Pathologist
- Philippe Gaulard, Anatomic Pathologist
- Jean-Pierre Bellocq, Anatomic Pathologist
- Brigitte Sigal, Anatomic Pathologist
- Séverine Alran, Surgeon
- Anne de Roquancourt, Anatomic Pathologist
- Jean Cuisenier, Surgeon
- Corinne Haioun, Hematologist
- Véronique Leblond, Haematologist
- Catherine Thieblemont, Haematologist
- Gilles Salles, Haematologist
- Henri Roche, Oncologist
- Pierre Kerbrat, Oncologist
- Alfred Fitoussi, Plastic Surgeon
- Nathalie Bricout, Plastic Surgeon
- Corinne Balleyguier, Radiologist
- Anne Tardivon, Radiologist
- Guy Launoy, Public Health Physician
- Ignacio Garrido-Stowhas, Plastic Surgeon
- Patrice Viens, Oncologist
- Martine Meunier, Radiologist
- Mario Campone, Oncologist
- Georges Delsol, Anatomic Pathologist
- Henri Tristant, Radiologist

**Also present to provide further details to the discussions of the group of experts:**

- **Jean-Claude Ghislain, Bernard Delorme, and Christiane Angot from AFSSAPS**
- **Arlette Danzon from INVS.**