



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

14.02.2014

Information on Poly Implant Prothèse (PIP) Breast Implant Referral

Dear Primary Care Team Member / General Practitioner,

You will be aware of recent reports regarding Poly Implant Prothèse (PIP) Breast Implants and information published by the Irish Medicines Board on identified health risks associated with these implants (see <http://www.imb.ie/EN/News/Poly-Implant-Prosthese-PIP-breast-implant-update.aspx>)

The summary findings from two international reports on this issue are presented in Appendix 1. These findings highlight that there are no medical, toxicological or other data to justify removal of an intact PIP implant. It is important that any concerned patient is provided with this information.

Where a woman presents to a PCT / GP and requires a clinically necessary referral or you identify issues associated with a **PIP breast implant** in a presenting patient, you should refer this patient to one of the 8 designated breast services nationally where necessary assessment and clinical treatment will be provided. For your information these centres are listed in Appendix 2.

To ensure clarity, referral to designated breast centres should only be made for PIP breast implants where the original primary consultant is not available to provide appropriate treatment. Issues or concerns about all other (non-PIP) breast implant patients should be referred to their primary treating consultant in the first instance.

Should removal of a PIP breast implant be clinically necessary this will be actioned but replacement cosmetic implants will not be funded.

Yours sincerely,

A handwritten signature in black ink that reads "Ciaran Browne".

Ciaran Browne
HSE

Appendix 1 – Findings from International Reports

European Commission on Scientific Committee on Emerging and Newly Identified Health Risks
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_038.pdf

Summary findings:

- The risk of implant rupture increases with implantation time.
- In some cases, implant gel-bleed or rupture has been associated with an inflammatory reaction either locally or in regional lymph nodes. In other cases, ruptures were free of symptoms. Neither implant rupture, nor local inflammation, has been found to be associated with breast cancer or anaplastic large cell lymphoma. While there are differences in rupture rates, there is no reliable evidence that ruptured PIP implants create a greater health risk than a ruptured silicone breast implant from another manufacturer.
- In the case of implant rupture, explantation is advised. Because of the widespread concern of undetected ruptures, there is a need for women with PIP breast implants to seek regular clinical examinations, and where deemed appropriate, individual counselling and imaging with ultrasonography or MRI.
- There is currently no convincing medical, toxicological or other data to justify removal of intact PIP implants as a precautionary approach. Implant removal in the absence of malfunction may be considered for women who are experiencing significant anxiety because they have a PIP breast implant. However, the decision to remove an intact PIP implant for this reason should be based on an individual assessment of the woman's condition by her surgeon or other treating physician after consultation.

NHS Expert Working Group Chaired by Sir Bruce Keogh

<http://www.nhs.uk/conditions/breast-implants/Documents/PIP%20expert%20group%20final%20report.pdf>

Summary findings:

- rigorous world-wide chemical and toxicological analyses of a wide variety of PIP implants have not shown any evidence of significant risk to human health
- there is no reason to believe that further testing will change this conclusion, given the results of the chemical analysis and the number of batches that have now been tested world-wide, which have all reached a similar conclusion;
- PIP implants are significantly more likely to rupture or leak silicone than other implants, by a factor of around 2-6, and this difference is detectable within 5 years of implantation;
- in a proportion of cases, failure of the PIP implant results in local reactions but these are readily detected by outward clinical signs – “silent” ruptures (ruptures which come to light only on explantation) are not generally associated with these local reactions

Appendix 2 – List of Designated Breast Units

1. Mater Hospital, Dublin
2. St Vincent's University Hospital, Dublin
3. St. James's Hospital
4. Beaumont Hospital, Dublin
5. Waterford Regional Hospital
6. Cork University Hospital
7. Mid Western Regional Hospital, Limerick
8. University College Hospital Galway