IRISH MEDICINES BOARD

Notice Information: - Advisory
26 May 2011

Part 1. Product Information

a)	Title:	Silicone Gel filled Breast Implants manufactured by Poly Implant Prothese (PIP). (All models and lot numbers)
b)	Product Name/Type:	Silicone Gel filled Breast Implants manufactured by Poly Implant Prothese (PIP). (All models and lot numbers)
c)	Reference:	IMB Safety Notice: SN2011(09)
d)	Manufacturer/Supplier:	Poly Implant Prothese (PIP)

Part 2. Target Audience

a)	Target Audience:	Medical directors Plastic surgeons and all surgeons involved in breast reconstruction Directors of surgical units involved in breast surgery Breast Surgeons General practitioners Practice managers Practice nurses Private Cosmetic Clinics

Part 3. Problem/Issue

a)	Problem/Issue:	The latest test results confirm no evidence of genotoxicity or chemical toxicity of the filler material in breast implants manufactured by the French company Poly Implant Prothese (PIP).

Part 4. Background Information

a) Background Information:

This Safety Notice is an update to the IMB Safety Notice SN2010(13) issued on the 5th October 2010 (see attached). Please refer to the Safety Notice SN2010(13) for further information on the background of the issue concerning the PIP implants.

On the 14th April 2011, the French medical device regulatory authority AFSSAPS published results of the additional testing that was conducted with the PIP implants. These results confirm that there is no evidence of genotoxicity or chemical toxicity of the filler material in these implants.

http://www.afssaps.fr/content/download/33144/435175/version/2/file/PIP

Further details can be found at the following link (in French only):

http://www.afssaps.fr/Dossiers-thematiques/Implants-mammaires-PIP-pre-remplis-de-gel-de-silicone/Contexte-de-la-decision-de-police-sanitaire-du-29-mars-2010/(offset)/0

Tests on the PIP implants have been conducted by several Regulatory Agencies, including the Therapeutic Goods Administration (TGA) in Australia, Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and the AFSSAPS.

Please refer to the IMB Safety Notice SN2010(13) for further information on the testing performed and test results.

The IMB will continue to closely monitor this matter in liaison with our colleagues in Europe.

Part 5. Action to be taken

a) Action to be taken:

The IMB recommends that:

Implanting surgeons / implanting centres

1. Ensure that all patients who were implanted with PIP silicone filled implants are advised of the content of this safety notice and the previous safety notice that was issued by IMB, Safety notice SN2010(13).

2. Highlight the key findings to the patient:

• Test results show no evidence of genotoxicity or chemical toxicity of the filler material in the implants.

• Mechanical testing of the implant shell carried out by AFSSAPS confirmed that there may be

an increased risk of rupture.

GPs

Advise patients who are concerned about their PIP implants to consult their implanting surgeon/ implanting centres.

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie Please Click here to downlaod a PDF version of the Safety Notice