IRISH MEDICINES BOARD

Notice Information: - Advisory
05 October 2010

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: SN2010(13)
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 construction General practitioners Practice managers Practice nurses Private Cosmetic Clinics

Part 3. Problem/Issue

a)	Problem/Issue:	A recall of silicone gel filled breast implants manufactured by the French company Poly Implant Prothese (PIP) was initiated in Ireland on the 30th March 2010. The recall follows a manufacturing site inspection in France which identified unauthorised silicone gel being used in the product.

Part 4. Background Information

a) Background Information:

In March of this year the IMB was informed by the French medical device regulatory authority (AFSSAPS) that they suspended Poly Implant Prothese (PIP)'s the marketing, distribution and export of these products. This action was taken following an inspection of PIP's manufacturing plant where it was found that most implants manufactured since 2001 were filled with an unauthorised silicone gel which differs in composition from the originally approved material.

The inspection conducted by AFSSAPS was prompted when an increase in the number of incident reports regarding device rupture and local complications associated with these products was noted in France.

At the time of the recall the IMB ensured that all Hospitals /Clinics in Ireland that used these devices were advised of the issue. The IMB advised these facilities to cease the use of these products.

To date the IMB has received one confirmed adverse incident associated with the use of this device.

Since the issue was identified in March the IMB has closely monitored the situation in liaison with our colleagues in Europe to determine potential safety implications.

Tests on the affected 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 French Regulatory Agency, Afssaps.

On July 2010 the Department of Health and Ageing, Therapeutic Goods Administration in Australia issued the following results

www.tga.gov.au/alerts/devices/silicone.htm

The results of TGA testing to date indicate that the PIP breast implants supplied in Australia conform to the relevant international standards for this type of product including those for gel cytotoxicity and shell strength. On the 3rd September 2010 the Medicines And Healthcare products R

On the 3rd September 2010 the Medicines And Healthcare products Regulatory Agency in the UK advised the following

http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON093706

The tests found no evidence of genotoxicity (potential for cancer) or chemical toxicity of the filler material in the implants.

On the 4th October 2010 the Medicines And Healthcare products Regulatory Agency in the UK issued the following recommendations to Surgeons

http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON096755

On the 27th September the French Regulatory Agency AFSSAPs released their investigation findings.

http://www.afssaps.fr/var/afssaps_site/storage/original/application/38fbe37bdd1897eb09de4f892a317c14.pdf

The physicochemical analysis confirm that gels filling tested breast implants of PIP company are not those described in the manufacturer's design file.

Two tests of mechanical strength are compliant with requirements of existing standards for breast implants. However the test for elongation until rupture is not in accordance with the standards.

A test shows that the gel of PIP breast implants has no acute toxic effects on tissues (cytotoxicity).

The results of the intradermal irritation test show an irritant behaviour o

PIP gel that is not found on other silicone gels of other breast implants.

Three tests for assessing possible effect of the PIP gel on DNA of the cells (genotoxicity) were carried out, 2 in vitro and 1 in vivo in mice. If both in vitro tests have shown negative results, finding obtained in vivo do not allow in the present state to conclude on the absence or presence of a genotoxic effect.

Further testing will be conducted by Afssaps with results expected early in 2011. The IMB will continue to closely monitor this issue with AFSSAPS and our other regulatory colleagues

Part 5. Action to be taken

a) Action to be taken:

The IMB recommends that:

Implanting surgeons / Implanting centres

• Identify women who were implanted with PIP silicone gel filled implants after 01 January 2001.

• Reassure them that there is no current evidence of health risk associated with the implants.

• Advise them that further information about the testing is available on the IMB, Therapeutic Goods Administration in Australia, Medicines And Healthcare products Regulatory Agency in UK and French Regulatory Agency AFSSAPs websites. (web addresses provided above).

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 download PDF version of Safety Notice