POLY IMPLANT PROSTHESES (PIP) BREAST IMPLANTS: INTERIM REPORT OF THE EXPERT GROUP

Sir Bruce Keogh, NHS Medical Director

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Document Purpose	Action
Gateway Reference	17083
Title	PIP BREAST IMPLANTS: INTERIM REPORT OF THE EXPERT GROUP
Author	SIR BRUCE KEOGH, NHS MEDICAL DIRECTOR
Publication Date	**06 January 2012**
Target Audience	PCT Cluster CEs, NHS Trust CEs, Foundation Trust CEs , Medical Directors, PCT Cluster Chairs, NHS Trust Board Chairs, Directors of Finance, GPs, Communications Leads, General public and media
Circulation List	
Description	Interim report of the expert group convened under the chairmanship of Sir Bruce Keogh to review policy in relation to breast implants from the French company Poly Implant Prostheses (PIP).
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	**Immediate**
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For Recipient's Use	

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First published [Month Year]
Published to DH website, in electronic PDF format only.
www.dh.gov.uk/publications

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Poly Implant (PIP) Breast Implants: Interim Report of the Expert Group

Introduction

This is the interim report of the expert group convened under my chairmanship to review policy in relation to breast implants from the French company Poly Implant Prostheses (PIP). The members of the group are listed at Annex A.

2. The overriding concern of the group is the safety and compassionate treatment of women with PIP breast implants. In our report we

i review the available data on the health risks from PIP implants

ii conclude that there is no clear evidence at present that patients with a PIP implant are at greater risk of harm than those with other implants, and we therefore agree with the MHRA advice that there is no specific safety concern identified which requires a recommendation of routine removal of PIP implants

iii recognise the anxiety of many women who received PIP implants in good faith on the assumption that they were manufactured in accordance with EC standards

iv commend and endorse the decision of DH ministers that, where women have received a PIP implant as part of NHS treatment, they will be contacted to inform them that they have a PIP implant and to provide relevant information and advice; and will be offered further procedures subject to clinical need and taking full account of the wishes and concerns of the patient.

v expect private sector providers to take similar action

vi the available evidence is subject to considerable uncertainty and therefore we recommend the collection of additional information which will enable the group reach a more informed view.

A summary of our provisional conclusions and recommendations for further work is at Annex B.

3. The group will reconvene in about 4 weeks' time to review any new evidence and to consider whether this advice needs to be amended.

Background

4. Breast implants are regulated under a European Union Medical Device Directive[i]. See Annex C for further details.

5. PIP received a CE mark for their silicone gel breast implants in 2000 via the German Notified Body TUV Rheinland and started exports to the UK in that year. Between 2001 and 2009 about 80,000 implants (representing some 40,000 women) were sold in the UK and, to date, some 478 adverse incident reports have been received. This rate of incidents was not considered to be significantly different from that for other brands of implant.

6. From about 2006 onwards, concerns began to emerge among cosmetic surgeons about the performance of PIP implants[ii]. In 2008 the MRHA noted an increase in the number of reports of ruptures and raised concerns with the manufacturer and the notified body, but this was understood to be the result of an increase in sales and improvements in the manufacturer's reporting criteria. The MHRA raised further concerns in 2009. In March 2010 the French regulator Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS), discovered that the manufacturer had been using industrial grade silicone instead of the medical grade specified for the CE mark. AFSSAPS revoked the CE mark and the MHRA promptly issued a medical device alert to all UK clinicians and cosmetic surgery providers, asking them to cease using the implants.

7. Toxicology tests on samples of filler material in both France and the UK suggested that there was no significant health risk to women who had already received the implants.

8. On 20 December 2011, following a large increase in the number of reported ruptures and concerns over a possible cancer risk, AFSSAPS wrote to European competent authorities (ie regulatory bodies) alerting them to the new data. On 23 December the French Ministry for Health announced that it was advising women, as a precautionary measure, to consider explantation[iii]. After consideration of the evidence reported within the UK and consultation with other countries known to have used PIP implants, the MHRA issued interim advice. This suggested that, on the available data, women in the UK should not be advised to seek explantation in the absence of clinical symptoms[iv].

9. Our immediate task was to review the available data, including further information from the French authorities[v] and to consider whether there is a need to revise the current advice in the UK.

Issues considered by the group: (i) safety issues

10. The first set of issues considered by the group was whether, on the balance of evidence, women with PIP implants who have no current symptoms should be advised as a precautionary measure to seek an explantation, or should be advised (as at present) to wait for the possible development of symptoms that might indicate a rupture. This involves balancing the risks associated with PIP implants, including the risks resulting from possible rupture of the implant, against the risks of undertaking explantation surgery earlier than might otherwise be necessary.

The cancer risk

11. The expert group **consider that, on the available data, there is no evidence that PIP implants are associated with a higher risk of breast cancer than other silicone gel implants**. This is in line with the advice of the French National Institute for Cancer (INCA)[vi]

that "the number of breast cancers seen in women with PIP implants is less than the levels for the general population".

12. In February 2011 MHRA issued a safety alert[vii] on the possible, but very low risk, link to anaplastic large cell lymphoma of silicone gel implants in general. No cases have been recorded in the UK.

The significance of the use of industrial grade silicone rather than medical grade silicone in implants

13. The composition of silicone used by PIP during the period of manufacture is not certain. However, **it is clear that the material used cannot be guaranteed to have been submitted to the same rigorous toxicological testing as is required to meet the essential requirements of the Directive. We can draw no conclusions from this about its quality in the context of breast implants.**

Signs and symptoms of rupture

14. Guidance on signs and symptoms of rupture has been prepared as part of our guidance to clinicians - see paragraph 29 below.

Health consequences of a rupture

15. Breast implant ruptures, or leaks of gel, may result in inflammation of the surrounding tissues. The tissue responses may be reflected by lumpiness, swelling and discomfort in the local or regional tissues. Other signs of rupture include changes in the shape, consistency and symmetry of the breast. According to the AFSSAPS data as at 28 December[viii], some 495 women with PIP implants have suffered an inflammatory reaction, or about 1.7% of the estimated 30,000 women in France with such implants. We are not aware of any available estimates for other implants against which we could compare this figure.

16. Since the 1970 breast implants have evolved through a number of evolutionary stages/ generations. Contemporary implants contain a cohesive gel in which the polymer is cross linked and the gel "form stable". This cohesive characteristic of the gel reduces the risks associated with rupture as the gel is "held together" and is less likely to migrate into the breast tissues or the lymphatic system. It appears that the gel within PIP implant is significantly less cohesive than other contemporary implants. The implications of this include a greater tendency to interface with the local tissue and a greater potential to generate an inflammatory response. There is also some data supporting an increased risk of in vivo transdermal irritation from PIP implants. Members of the UK professional bodies for cosmetic surgery for cosmetic surgery report anecdotal evidence that, when a PIP implant ruptures, silicone gel is more widely dispersed in surrounding tissue and the resulting explantation is more difficult and more involved. This could result in a more prolonged hospital stay with additional risks. Two case studies have been published[ix] although it appears in these two cases that there were no long-term effects on health.

17. Laboratory tests on samples from PIP implants, both in the UK and in France, have shown no significant evidence of mutagenicity (potential to cause cancerous mutations). One test reported from France found that gel from PIP implants was more likely to cause an inflammatory reaction in rodents than standard, medical grade, silicone gel.

The risk of ruptures

18. Much attention so far has been given to the issue of rupture in breast implants. The cumulative risk of rupture of a breast implant increases progressively over time. An analysis published by the FDA[x] showed that the rupture rate for the Allergan implant is 0.5% after 2 years, rising to 10.1% (cumulative) after 10 years. For Mentor implants, the post implantation failure rate at 8 years was 13.6% (cumulative). It follows that quoting a "rate of rupture" for an implant, without specifying the time since the original implant, is unhelpful and potentially misleading.

19. There is no data on PIP implants of comparable quality to the FDA study mentioned above. We invited the sector to send us recent comparative data on PIP and other silicone breast implants (Annex D) and have concluded we can place no reliance upon these figures, which for non PIP implants are inconsistent with the FDA study by a fivefold factor. **More work clearly needs to be undertaken by the sector to ensure that more reliable data can be produced in future**.

20. There are a number of other difficulties in comparing risks of rupture for PIP and other implants:

i much of the available information is subject to potential under-reporting. Although the manufacturers are required to report all serious adverse events (including rupture), notifications from providers in the UK to the regulator are voluntary. Cosmetic surgery providers will only be aware of problems if patients come back to them for follow-up, and many patients may seek advice elsewhere (including the NHS). We believe that under-reporting seriously affects the validity of current PIP data and some comparative data about similar implants;

ii it is not clear whether all PIP implants have been affected by the use of substandard silicone to the same extent. For instance, it has been suggested that PIP continued to use medical-grade silicone in the implants supplied to Australia, so the apparently reassuring data from the Australian regulator may not be a valid guide to risks in the UK;

iii some ruptures – perhaps as many as 2 in 3 – do not result in clinical signs or symptoms, and can only be detected by scanning or by explantation (removal). Ruptures reported after explantation, such as the recent data on PIP implants from the French regulators, cannot therefore be compared directly with data from routine reporting on other implants.

21. On the currently available information, the group **considers that the statistical evidence on the rate of ruptures for PIP implants compared with other implants is incomplete and this risk cannot be assessed accurately. For this reason it is unable to come to any view on comparative rupture rates. We attach the data received at Annex D.**

Risks associated with explantation

22. As noted above, a full assessment of the safety aspects of PIP implants involves balancing the risks associated with leaving the implants in place against the risks of undertaking explantation surgery earlier than might otherwise be necessary. In this context, it is worth bearing in mind that all breast implants have a finite life – data from the FDA suggest that 1 in 5 cosmetic breast implants, and 1 in 2 breast implants following reconstruction surgery, are explanted or replaced within 10 years.

23. Women who receive breast implants are, in general, a very healthy sector of the population. Advice from the Royal College of Anaesthetists is that the risk of anaesthetic mortality in healthy adults is of the order of 1 in 100,000[xi] to 1 in 250,000[xii]. If all 40,000 women in the UK with PIP implants had explantation surgery, the estimated excess deaths would therefore be about 0.4 or less. The available literature[xiii] confirms the view of members of the expert group that there are no significant risks of morbidity associated with explantation *per se* over and above the risk of the original operation..

Issues considered by the group: (ii) practical clinical issues

24. Whatever the objective evidence on safety, many women with PIP implants will understandably be very worried about the possible implications for their health. In itself, this anxiety is a form of health risk and must be addressed with understanding and compassion by those responsible for their treatment.

25. Women who received PIP implants will have been informed about the risks associated with breast implants in general, in line with current best practice guidance[xiv]. They will however have assumed, in good faith, that the material to be used in the implants was medical grade silicone, in line with the CE mark. Now that we know that a substantial proportion of PIP implants have used industrial grade silicone, we believe that there **is a duty of care on the part of the providers of surgery to offer these women whatever is reasonably needed to reassure them that they will not suffer long-term health effects as a result of the deception by PIP**.

26. A minority of women with PIP implants have received these implants as a result of reconstruction surgery carried out by the NHS, eg following surgery for breast cancer. Ministers have already made clear that:

- All women who have received a PIP implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant then this will be provided free of charge;
- Women who wish to will able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward;
- If the woman chooses, this could include a non-urgent examination by imaging to see if there is any evidence that the implant has ruptured;
- The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk and the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

27. **The group endorses this offer. It expects providers in the private sector to take similar steps** (as one major provider, the Nuffield Hospital Group, has already signalled)[xv].

28. Clinicians, in advising women, should make clear that (on current evidence) explantation would be a precautionary measure rather than because of a definite risk to health.

29. Guidance to GPs and surgeons, on the clinical indications that an urgent referral might be needed in relation to concerns about any implant of this type, is attached at Annex E.

30. Where patients find that their private sector provider is no longer in practice, the group considers that **in the event of their approaching the NHS and where the clinical need has been identified, only non-urgent removal - rather than removal and replacement - should be offered**.

Issues considered by the group: (iii) equalities implications

31. We have considered whether the public sector equality duty in s149 of the Equality Act 2010 is relevant to our deliberations, and whether anyone sharing a 'protected characteristic' listed under that legislation will be subject to special disadvantage. Protected characteristics include age, disability, gender, gender reassignment status, marriage and civil partnership status, pregnancy and maternity status, race, religion or belief, and sexual orientations.

32. We have concluded that **there is no evidence to support a conclusion that anyone sharing a protected characteristic as described above is subject to special disadvantage**.

Further work

33. Further information is needed in particular on the risks associated with the rupture of PIP implants and the resulting inflammatory reaction. The **group will be reconvened to review these issues and to consider whether any change is needed to our advice.**

34. As a second stage, the Secretary of State has asked me to prepare a report on the lessons learned from this issue including:

i current arrangements for the monitoring of the safety of breast implants and other implantable devices, including the proposal from professional organisations to re-establish the breast implant registry which the department discontinued in 2007;

ii the regulation and governance of the cosmetic surgery industry.

35. I propose that this further review should be undertaken by a reconstituted review group, including the organisations represented in this expert group with additional membership from the independent healthcare industry, the CQC and the NPSA.

Sir Bruce Keogh
NHS Medical Director

January 6 2012

References:

[i] Medical Devices Directive 93/42/EEC
[ii] Lahiri and Waters *Journal of Plastic, Reconstructive and Anaesthetic Surgery* (2006) **59** 85; Berry *British Journal of Plastic Surgery* (2007) 968
[iii] Press release from French ministry of work, employment and health 23 December 2011
[iv] MRHA press release of 23 December 2011
[v] AFFSAPS Press release of 30 December 2011
[vi] Report of the Institut National du Cancer (INCa), 22 December 2011
[vii] MHRA safety alert Feb 2011
[viii] See reference 5
[ix] See references at 2 above
[x] FDA core studies on the Allergen and Mentor implants
[xi] Royal College of Anaesthetists risk information leaflet October 2009
[xii] S Fasting, abstract cited from http://www.hopkinsguides.com/hopkins/ub/citation/20224619/%5BRisk_in_anaesthesia%5D
[xiii] Siggelkow et al 2004
[xiv] FDA Update on safety in silicone gel fitted implants, June 2011
[xv] Nuffield Health, press release 4 January 2011

ANNEXES

Annex A: Members of the expert group

Sir Bruce Keogh (NHS Medical Director) – Chairman

Mr Fazel Fatah (Consultant Plastic Surgeon, President British Association of Aesthetic Plastic Surgeons)

Mr Tim Goodacre (Consultant Plastic Surgeon, President British Association of Plastic Reconstructive and Aesthetic Surgeons)

Sir Ian Kennedy

Professor Ian Kimber (Professor of Toxicology, Manchester University, Toxicology member of the Committee on the Safety of Devices)

Mr Ian Martin (President of the Federation of Surgical Specialist Associations)

Mr Richard Rainsbury (Consult Surgeon, President of the Association of Breast Surgery)

Dr Anne-Marie Slowther (Associate Professor of Clinical Ethics, Warwick Medical School, Consultant Clinical Ethicist, University Hospitals, Coventry and Warwickshire NHS Trust)

Professor David Spiegelhalter (Professor of Bio Statistics and Winton, Professor of the Public Understanding of Risk)

Dr Andrew Vallance-Owen (Medical Director, BUPA)

Professor Norman Williams (Professor of Surgery and Director of Surgical Innovation at Barts and The London School of Medicine and Dentistry, President of the Royal College of Surgeons of England)

Mr Simon Edwards (Head of Policy Royal College of Surgeons of England)

Mr Simon Withey (Consultant Plastic Surgeon, Member of Council of British Association of Aesthetic Plastic Surgeons, Member of the Steering Committee looking at Standards in Aesthetic Plastic Surgery)

Annex B: Provisional Conclusions and Recommendations for Further Work

The expert group:

- Considers, on the available data, that there is no evidence that PIP implants are associated with a higher risk of breast cancer than other silicone gel implants.

- Finds it clear that the composition of silicone used by PIP during the period of manufacture cannot be guaranteed to have been submitted to the same, rigorous toxicological testing as is required to meet the essential requirements of the Directive. We can draw no conclusions from this about its quality in the context of breast implants.

- Agrees that more work clearly needs to be undertaken by the sector to ensure that more reliable data on silicon breast implants can be produced in future.

- Considers that the statistical evidence on the rate of ruptures for PIP implants compared with other implants is incomplete and this risk cannot be assessed accurately. For this reason it is unable to come to any view on comparative rupture rates.

- Believes that there is a duty of care on the part of the providers of surgery to offer these women whatever is reasonably needed to reassure them that they will not suffer long-term health effects as a result of the deception by PIP.

- Endorses the offer made by Ministers to women with PIP implants who have received these implants as a result of reconstruction surgery carried out by the NHS, eg following surgery for breast cancer.

- Expects providers in the private sector to take similar steps.

- Considers that in the event of private sector patients approaching the NHS and where the clinical need has been identified, only non-urgent removal, rather than removal and replacement should be offered.

- Has concluded that there is no evidence to support a conclusion that anyone sharing a protected characteristic as described in the Equalities Act 2010 is subject to special disadvantage.

- The group will be reconvened after further information is received to review the risks associated with the rupture of PIP implants and the resulting inflammatory reaction and to consider whether any change is needed to our advice.

In addition, a further review will be undertaken by a reconstituted review group, including the organisations represented in this expert group with additional membership from the independent healthcare industry, the CQC and the NPSA, to consider:

- current arrangements for the monitoring of the safety of breast implants and other implantable devices, including the proposal from professional organisations to re-establish the breast implant registry which the department discontinued in 2007; and

- the regulation and governance of the cosmetic surgery industry.

ANNEX C: REGULATION OF MEDICAL DEVICES

There are over 90,000 types of medical device on the market in the UK. These are regulated under the provisions of the European Medical Devices Directives.

Medical device regulation differs substantially from the regulation of medicines. The safety of medical devices is assessed by independent third party organisations. The licensing of medicines is undertaken by state regulators such as the Medicines and Healthcare Products Regulatory Agency (MHRA).

All medical devices such as breast implants require a CE mark of conformity before they can be marketed in Europe. For all but the lowest risk devices the CE mark must be authorised through assessment by an independent third-party organisation, known as a notified body. There are over 80 of these notified bodies across Europe.

Each notified body is appointed and audited by the Competent Authority (regulatory authority) in their respective country. A manufacturer can select any notified body across Europe irrespective of location, provided that their field of expertise covers the device being considered. Once a CE mark is applied the medical device can be sold in all EU countries without further controls.

The regulations are implemented by a Competent Authority in each member state. In the UK this is the MHRA. The role of the Competent Authority is to implement the provisions of the directives, to appoint and control notified bodies and to monitor and investigate adverse events occurring in their country. In the UK this involves investigating both mandatory serious adverse event reports from manufacturers and adverse events reported voluntarily by healthcare professionals and members of the public. As a result of these investigations MHRA will take further action as appropriate including recalling faulty products (safeguard action) and offering advice to the health service through Medical Device Alerts.

ANNEX D: PIP IMPLANT DATA SUPPLIED BY UK COSMETIC SURGERY PROVIDERS TO MHRA BY 5PM ON 5 JANUARY 2012

For cautions on the interpretation of the data, see paragraphs 18 – 21 in the report.

The following tables set out the data returned by providers to the MHRA before 5pm GST on 5 January 2012. Further data received will be taken into account

BMI Healthcare

Date of first implantation	2002

Year of post-operative experience	**Number of women with this post operative experience**	**How many women have had explants due to rupture during this post implant year?**
1st year	230	1
2nd year	192	1
3rd year	166	0
4th year	381	0
5th year	141	0
6th year	88	1
7th year	44	1
8th year	58	6
9th year	11	4
10th year	0	0

County Durham and Darlington NHS Foundation Trust

Date of first implantation	

Post-operative year	Number of women	How many women have had explants due to rupture during this post implant year?
1st year	72	
2nd year	94	
3rd year	121	
4th year	118	
5th year	110	
6th year	35	
7th year	0	
8th year	0	
9th year	0	
10th year 2011	0	

Harley Medical Group

Date of first implantation	Jan-00

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	11837	4
2nd year	11160	28
3rd year	8838	72
4th year	6010	79
5th year	3875	60
6th year	2024	53
7th year		
8th year		
9th year		
10th year		

IHAS – Court House Clinics

Date of first implantation	20/01/2004

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?

1st year	3	
2nd year	12	1
3rd year	20	
4th year	20	
5th year	27	1
6th year	22	
7th year	37	
8th year		
9th year		
10th year		

IHAS – Make Yourself Amazing

Date of first implantation	29/07/2007

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	0	0
2nd year	0	0
3rd year	1	0
4th year	3	0
5th year	44	4
6th year	0	0
7th year	0	0
8th year	0	0
9th year	0	0
10th year	0	0

IHAS- Aspen

Date of first implantation	2000

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	36	0
2nd year	40	0
3rd year	43	0

4th year	11	0
5th year	4	0
6th year	3	0
7th year	1	0
8th year	3	0
9th year	2	0
10th year	0	0

IHAS – Bridgewater Hospital

Date of first implantation	17.05.2007

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	6	
2nd year	2	
3rd year		
4th year		
5th year		
6th year		
7th year		
8th year		
9th year		
10th year		

Linia Cosmetic Surgery

Date of first implantation	2.04.2003

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	0	0
2nd year	0	0
3rd year	21	3
4th year	147	6
5th year	148	1
6th year	150	8
7th year	104	1

8th year	277	2
9th year	0	0
10th year	0	0

Mid-Cheshire Hospitals NHS Foundation Trust

Date of first implantation	

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year		
2nd year		
3rd year		1
4th year		
5th year		
6th year		
7th year		
8th year		
9th year		
10th year		

Mid-Essex Hospital Services NHS Trust

Date of first implantation	

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year	0	
2nd year	0	
3rd year	0	
4th year	0	
5th year	0	
6th year	0	
7th year	0	
8th year	0	
9th year	0	
10th year	0	
11th year	0	1

New Victoria Hospital

Date of first implantation	1998

Year of post-operative experience	**Number of women with this post operative experience**	**How many women have had explants due to rupture during this post implant year?**
1st year	5	0
2nd year	5	0
3rd year	7	0
4th year	14	0
5th year	22	0
6th year	2	0
7th year	0	0
8th year	0	0
9th year	0	0
10th year	1	0

NHS Herefordshire West Mercia

Date of first implantation	

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year		
2nd year		
3rd year	1	
4th year		
5th year		
6th year		
7th year		
8th year		
9th year		
10th year		

North Tees and Hartlepool NHS Foundation Trust

Date of first implantation	2000

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year	2	1
2nd year		
3rd year		
4th year		
5th year		1
6th year		
7th year	11	
8th year		
9th year		
10th year		
11th year		3
12th year		2

Royal Cornwall Hospitals Trust

Date of first implantation	

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year		
2nd year		
3rd year		1
4th year		1
5th year		1
6th year		
7th year		
8th year		

9th year		
10th year		

Spire Healthcare

Date of first implantation	1999

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	1	0
2nd year	18	1
3rd year	108	1
4th year	113	1
5th year	158	2
6th year	278	10
7th year	308	15
8th year	273	4
9th year	131	4
10th year	32	1

The Christie NHS Foundation Trust

Date of first implantation	N/A

Post-operative year	Number of Implants	How many women have had explants due to rupture during this post implant year?
1st year	0	0
2nd year	0	0
3rd year	0	0
4th year	0	0
5th year	0	0
6th year	0	0
7th year	0	0
8th year	0	0
9th year	0	Not Determined

10th year	0	Not Determined

Transform

Date of first implantation	2004

Year of post-operative experience	Number of women with this post operative experience	How many women have had explants due to rupture during this post implant year?
1st year	2939	2
2nd year	1232	1
3rd year	52	6
4th year	21	17
5th year	27	17
6th year	5	42
7th year	5	45
8th year		17
9th year	0	
10th year	0	0

University Hospitals Coventry and Warwickshire

Date of first implantation	Never

Post-operative year	Number of women	How many women have had explants due to rupture during this post implant year?
1st year		
2nd year		
3rd year		
4th year		
5th year		
6th year		
7th year		1
8th year		
9th year		
10th year		

University Hospital of South Manchester

Date of first implantation	2000

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year	1	0
2nd year		0
3rd year		0
4th year		0
5th year		0
6th year		0
7th year		0
8th year		0
9th year	1	0
10th year	2	0

The Trust does not use PIP implants. The Trust operated on patients with PIP implants for removal.

University College London Hospitals NHS Foundation Trust

Date of first implantation	1998

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1998	2	
1999		
2000	1	
2001		
2002	2	
2003		
2004		
2005		
2006		
2007		

University Hospitals of Morecambe Bay NHS Foundation Trust

Date of first implantation	N/A

Post-operative year	Number of women	How many women have had explants due to rupture during this post implant year?
1st year		
2nd year		1
3rd year		
4th year		
5th year		
6th year		
7th year		
8th year		
9th year		
10th year		

Warrington Hospitals NHS Foundation Trust

Date of first implantation	2006

Post-operative year	Number of women	How many women have had explants due to rupture during this post implant year?
1st year		
2nd year		
3rd year	1	1
4th year		
5th year	1	1
6th year		
7th year		
8th year		
9th year		
10th year		

Yeovil District Hospital

Date of first implantation	Jan-07

Post-operative year	**Number of women**	**How many women have had explants due to rupture during this post implant year?**
1st year		
2nd year		
3rd year		
4th year	1	1
5th year		
6th year		
7th year		
8th year		
9th year		
10th year		

ANNEX E: CLINICAL GUIDANCE FOR GPs AND SURGEONS

Patients: Any patient with breast implants is advised to check the details of their implant with their surgeon or clinic.

GPs consulted by patients with PIP implants should explore the patient symptoms and examine the breast and locoregional lymph nodes.
Patients with local signs and symptoms should be referred for a specialist opinion.
Signs will include

- Lumpiness of the breast
- Lumpiness/ swelling of the regional lymph nodes
- Change in shape of the breast
- Deflation of the breast
- Redness
- Tenderness of the breast
- Swelling of the breast

Symptoms may include

- Pain
- Hyperaesthesia

Guidance for GPs for NHS specialist referrals

Patients with PIP implants who experience lumpiness within the breast and lymph nodes : In cases where there is concern regarding the nature of the lumpiness, referral should be made to a rapid access breast service. In cases where the practitioner is happy that the lumps are associated with the implant or gel, referral should be made to the regional reconstructive breast surgery department
Patients with changes in shape or feel of the breast, for instance discomfort, deflation or asymmetry should be referred to their regional breast reconstructive unit. These patients do not require fast track referral.
Surgeons: Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or leak. Those patients who have evidence of implant rupture should be advised regarding the implications of implant removal/ exchange. If it is felt that the risk benefit ratio favours explantation/ exchange then this procedure should be advised. For NHS patients the patient may be offered re-implantation. For patients from the private sector who have been unable to secure help from their original

provider, the NHS will offer implant removal where it is felt to be clinically appropriate, but no re-implantation will be offered.
This guidance may change after consultation with relevant parties.

Guidance for GP referrals for private patients

General Practitioners may be approached by patients who underwent their surgery in the private sector. These patients should be advised to contact their original provider. It is expected by the expert group and the professional bodies represented on it that these providers will offer the same service as the NHS without cost to the patient.

Ongoing review

Where a patient decides, after consultation with her GP or specialist, not to have an explantation, she should be followed up on an annual basis. This review would normally be carried out by the GP (for NHS patients) or by the clinic which carried out the original implant (for private patients).