Australian Society *of* Plastic Surgeons

21 May 2012

Dr Ian Holland
Secretary
Standing Committee on Community Affairs

community.affairs.sen@aph.gov.au

Dear Dr Holland

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese breast implants

We are pleased to provide the additional information arising from questions on notice in relation to the above.

We also attach several background documents including:

- A copy of the ASPS proposed explant strategy provide for the CMO advisory group
- A copy of the ASPS Code of Practice and annual member declaration
- A copy of a presentation on the new Breast Device Registry

ASPS Recommendation to CMO Advisory Group on the Proposed Management of Patients with PIP Breast Implants (25 January 2012):

We attach this discussion paper for the information of the Senate Committee and in response to the questions posed by Senator Xenophon and Senator Moore relating to explanting the implants and, specifically, to questions about the level of patient anxiety.

The Recommendations Paper was prepared by Assoc Professor Rod Cooter, with the agreement of the ASPS Council, as a contribution to the Chief Medical Officer's Advisory Group consultation on the PIP situation. It was prepared in January 2012.

ASPS' mission is to support all Australians with best plastic surgical practice. This paper was therefore contributed as a discussion document. Some recommendations were agreed, such as, the provision of MRI scans and the recognition of patient anxiety being considered a complication.

The consensus of the Advisory Group was that, based on available data, even a conservative explant strategy such as the one proposed by ASPS, was not required.

While we respect the consensus, ASPS' view is that we would still propose an explant strategy in a carefully calibrated sequence to help those patients who want certainty.

ASPS Code of Practice 2011:

This Code of Practice was adopted by majority at a general meeting of members in November 2011 and supersedes the Society's previous "Guidelines for Professional Conduct". The new Code references: the "Good Medical Practice" Code of Conduct for Doctors in Australia issued by the Medical Board of Australia; the RACS Code of Conduct and Policy on Handling Breaches; AHPRA Guidelines; Federal and State laws; and Rules and Guidelines provided by various Federal and State regulatory and statutory authorities.

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The ASPS Code of Practice will be adopted (and adapted for local circumstances) by the New Zealand Association of Plastic Surgeons and the British Association of Plastic, Reconstructive and Aesthetic Surgeons.

Since the adoption of the ASPS Code of Practice in November 2011, there have been four formal complaints to the Ethics Committee:

- The Ethics Committee, under Rule 8.3 (a) responded to two separate complaints from members in respect to the advertising practice of other members. This resulted in the decision by the Ethics Committee to refer the complaints to AHPRA for its determination. Both complaints related to on line advertising of non surgical procedures which featured the use of incentives and special offers.
- The Ethics Committee facilitated the satisfactory resolution of a matter involving a complaint by a member in relation to another member's *'google'* search optimisation activity.
- A recent complaint has been received from a member of the general public in relation to an ASPS member. The Ethics Committee, under Rule 8.6, has referred the complaint in the first instance to the Society's legal team for advice.

Complaints received with regards to PIP implants and the manner in which they were handled:

ASPS has a small secretariat of 4 full time staff and 2 part-time staff. To the best of our ability we endeavoured to log all inquiries (email and phone) during the period January to April 2012. Our capacity to do so was often stretched particularly in December 2011 and early 2012 when media interest was intense. We estimate we fielded approximately 600+ inquiries including from our own members and the media in the period.

Inquiries by email and phone generally fell into the following categories:

<u>Breast Implant Registry (BIR)</u>

Inquirer: Checked if already registered on the Breast Implant Register (BIR) and if so, what implant was used. If not, requested to register.

ASPS' response: We followed prescribed protocols and provided patient details if registered and according to privacy provisions. If not registered we provided BIR forms and waived the levy to join the BIR (usually $25 per implant) for the period from 1 January to end March 2012 as a gesture to acknowledge the women were already anxious and we could at least take away that burden.

See attachment: Number of Inquiries on the impact of PIP on the BIR (excludes media and member inquiries).

<u>General Information</u>

Inquirer: Sought information about government response to PIP situation.

ASPS' response: We referred the inquirer to the TGA website and to the Department of Health and Ageing Help Line.

From ASPS members

We responded to and proactively communicated with our members, throughout 2010 - 2012. A chronology is attached. We posted updated information on our website for both the general public and our members.

Complaint about ASPS and how it has handled the PIP situation

Inquirer: We attach the only email that complained about how ASPS handled the PIP situation and also the potential cost to explant and replace. It also refers to symptoms of hair loss, chronic pain etc and implies a causal relationship with PIP implants.

ASPS' response: We attach the whole email trail as it demonstrates the issue and how ASPS responded (we removed the inquirer's name and email address for privacy reasons). Assoc. Professor Cooter personally replied, an extract in relation to fees states:

"You will be aware that the ACCC prohibits the price fixing of medical fees, in any circumstance, so we are not permitted by law to instruct our members to charge or not charge for the removal of PIP implants. Fees must be a matter of determination by individual medical practitioners. We have distributed all relevant and up to date information about the PIP situation to our members including confirmation, which we proactively sought from the head of Medicare, that there are circumstances in which certain item numbers may be used. That is, where patients present with a PIP implant, whether or not it is ruptured, circumstances could be such that it is reasonable to apply a Medicare Item number. Where this is not the case, I am personally aware of many instances in which our members have removed the PIP implants, free of charge, even though our member was in almost all cases, not the original implanting doctor. There are more than 300 members of our Society and all are fully trained specialist plastic surgeons and accredited as specialist surgeons by the Australian Medical Council. I would be pleased to see your evidence for your claim that, of our membership of 300 surgeons, *"the majority of ASPS plastic surgeons are charging full fees"*.

Complaint about an individual ASPS member surgeon

Inquirer: Our records show only two emails that name an individual plastic surgeon and complain, in both cases, about the cost of the quoted removal and replacement of the implants. One inquirer was seeking reduced costs for the explant of the PIP implant, replacement plus, simultaneously, a new breast related surgical procedure.

ASPS' response: We replied in writing and expressed empathy. We explained the Medicare Item numbers. We assured the inquirers that our ASPS members are committed to ensure that out of pocket expenses for removal and replacement of PIP implants are minimised for the patient however we could not fix prices as this would breach ACCC regulation. We also explained that costs are made up of various elements such as the surgeon's fee, theatre costs, anaesthetist fee, hospital stay etc. We suggested she return to the surgeon to seek a negotiated fee.

One inquirer replied and told us that the outcome was that she went back to the surgeon (ASPS member) and a reduced surgeon fee was negotiated.

Media

ASPS' secretariat, like many other organisations, received a large volume of media inquiries and request for interviews in the period December 2011 to April 2012 and the intensity varied.

Wherever possible we responded as soon as possible and the President was our spokesperson. Our interviews aimed to reduce anxiety and to provide relevant information.

Media outlets and journalists also directly contacted individual surgeons. ASPS' secretariat became aware of these through media monitoring reports.

Hansard transcript page 11, 2008 Correspondence between Medical Vision Australia and Dr Fleming re "PIP Titanium Coated Brest Implant Trial"

We note the attached letters in the Hansard transcript from Dr Fleming to Mr Stan Racic of Medical Vision Australia. However, we have no further information on this matter and can only acknowledge, as Assoc. Professor Cooter stated in the hearing, that he was aware of the trial but not involved with it after he examined the science at the PIP factory in 2005.

Supplementary information:

We believe that collaboration and cooperation with all practitioners for the development and implementation of a national opt out breast device registry is in the best interests of patient safety.

We attach a presentation on the Breast Device Registry which Assoc. Professor Cooter will make to a global summit of leaders of 15 national plastic surgical societies in Munich, 24 May 2012 which will present the formation of an International Collaboration of Breast Registry Activities. We are also invited by the President American Society of Plastic Surgery Societies to join a panel discussion with the FDA in October in New Orleans in relation to international cooperation around breast registries and specifically a minimum dataset.

We therefore welcome the verbal and written support of the Australasian College of Cosmetic Surgeons to our development of a new breast device registry and thank Dr Fleming for his comment, as recorded in the Hansard transcript, "We are keen to work with Monash and the Australian Society of Plastic Surgeons to develop this registry in such a way that that primary purpose is sacrosanct and not sacrificed".

We are also pleased to have been invited by Mr Colin Moore, President ACCS, to cooperate in the design and implementation of an audit study of the PIP MIRI data headed by Professor Emily Banks, ANU.

However, in the course of his evidence to the Committee, Dr Fleming also took the opportunity to comment on a number of issues raised by Assoc. Professor Cooter in his evidence to the Senate Committee. Many of the criticisms of ASPS raised by Dr Fleming have been well addressed and refuted in other more appropriate forums and, for the benefit of the Committee and relevancy to this inquiry, we do not intend to go over that old ground.

However, given Dr Fleming had the advantage to speak after Assoc. Professor Cooter and therefore took that opportunity to comment on Assoc. Professor Cooter's testimony, it is appropriate to address two specific matters recorded in the Hansard transcript:

1. **ACCS Code of Conduct**
   One page 22 of Hansard transcript, Dr Fleming states: "This code of conduct was vociferously opposed in the public submission process by the Australian Society of Plastic Surgeons and the Royal Australasian College of Surgeons. However, the ACCC did decide that it was in the public interest and it has now been in place for about three years".

While it is correct that the ACCC determined that "Authorisation" of the ACCS Code was in the public interest, this is a very different matter to the Code, in and of itself.

Codes of Conduct/Practice and Ethical Guidelines are a standard tool in the medical profession as indeed they are for many other professions. ASPS supports all efforts to improve patient safety and the quality of the patient experience and welcomes an ACCS Code of Conduct.

However, while not unique, it is unusual for membership bodies to seek ACCC "Authorisation" for voluntary codes of conduct. We were invited to be part of the ACCC consultation and ASPS did not agree that it was in the public interest that the ACCC grant "authorisation" of the ACCS Code.

Our legal advice at the time was that "authorisation", in the ACCC context, is a specific technical and legal term. It does not imply endorsement or approval of the Code or organisation. In simple terms, 'authorisation' can provide legal relief for the organisation, in certain circumstances, from allegations or claims made under the then Trade Practices Act by members who claim disadvantage as a result of discipline procedures under the ACCS Code.

In arguing against ACCC "authorisation", among other contributions made, ASPS believed that the term is not well understood by the general public and could potentially, and inadvertently, be confusing by implying special endorsement or approval by a highly respected regulatory body.

In our view, in effect, ASPS' participation in the ACCC consultation process proved to be of enormous benefit to ACCS, providing, as it did, a well articulated set of recommendations and suggestions as to how each iteration of the rolling series of drafts of the proposed Code could be further improved. This is well demonstrated by a comparison of the initial draft iteration of the Code compared with the final version.

As we stated earlier, good codes of ethics and practice are an essential part of good doctoring and patient safety and as such we are always pleased to support them.

2. Australian Medical Council (AMC) application for the creation of a new specialty

On page 21 and 22 of the Hansard transcript, D Fleming makes several statements in relation to the specialty of plastic surgery including its scope of practice, training and qualifications. We will not waste the Committee's time in going over the history but will correct specific errors of fact.

It is correct that in 2009 the ACCS lodged an application with the AMC for the "Recognition of Cosmetic Medical Practice as a new medical specialty". That decision is still pending.

It is also correct that that the AMC has already recognised the Specialty of Plastic Surgery, including its curriculum, as comprehensive of both cosmetic and reconstructive procedures. Royal Australasian College of Surgeons (RACS) is the only AMC accredited training body for medical specialists and it awards an AMC recognised Fellowship (FRACS) as the AMC approved qualification.

AHPRA deemed that titles must, first and foremost, reflect the level of AMC accreditation of the medical practitioner and not mislead the consumer. Hence the title, "General Practitioner" applies to a non specialist practitioner. The term "Specialist Plastic Surgeon" is the AHPRA protected title for those surgeons who have a FRACS in plastic surgery.

The AMC has not yet publicly handed down its decision in relation to the recognition of cosmetic medical practice as a new medical specialty. After the closure of the public consultation, ASPS has not been privy to the ongoing process of determination. At such time as the AMC determines to recognise, or not, a new specialty in cosmetic medical practice, ASPS, as consistently stated in the media and in its submissions to the AMC, will respect the decision of the Australian Medical Council.

It must also be noted that should the AMC "recognise" a new medical specialty called 'Cosmetic Medical Practice", this will be the first stage in a formal process of determination of the governance of the many associated aspects of a new specialty such as eligible training institutions, curriculum and the accreditation of qualifications.

Thank you again for the opportunity to meet the Senate Community Affairs Committee and to provide these follow-up responses.

We look forward to the final report.

Kind regards

Assoc. Professor Rodney Cooter MBBS. MD (Adel), FRACS
President

Enclosed:

1. ASPS Code of Practice
2. ASPS annual member declaration
3. ASPS Recommendation to CMO Advisory Group on the Proposed Management of Patients with PIP Breast Implants (25 January 2012)
4. Breast Device Registry – an International Perspective (May 2012)
5. The number of inquiries from the general pubic and the impact of PIP on the BIR
6. Email/ response to inquirer (name removed for confidentiality reasons)
7. Chronology of ASPS response to PIP situation 2010 - 2012

Australian Society
of Plastic Surgeons

Code *of* Practice 2011

AN ADJUNCT TO THE AMC AND RACS CODES OF CONDUCT

This Code of Practice provides specific guidance on the professional ethics and behaviour required of members of the Australian Society of Plastic Surgeons (ASPS). It reflects the professional standards expected of plastic surgeons by ASPS and the communities we serve. It focuses on particular issues and concerns relevant to the practice of plastic surgery, and assists Fellows and Trainees to respond appropriately to these issues and concerns.

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Members of ASPS, like all doctors in Australia, must comply with the "Good Medical Practice" Code of Conduct for Doctors in Australia issued by the Medical Board of Australia. The majority of ASPS members are also Fellows of RACS, and therefore subject to the RACS Code of Conduct and other relevant RACS standards and guidelines. This Code of Practice supplements the Medical Board of Australia and RACS Codes of Conduct by providing elaboration of key ethical and professional principles as they apply to plastic surgery.

Standards of behaviour help make our relationships mutually rewarding and productive, and ensure that patients receive the best possible standard of care. They remind us that the overarching concern of all medical practice is to act in the best interests of our patients to improve their health and quality of life.

The purpose of this Code is:

- to define acceptable behaviours in the practice of plastic surgery
- to promote high standards of practice and professional responsibility on the part of plastic surgeons
- to provide a benchmark for members to use for self evaluation
- to preserve the reputation and high standards expected of our profession

Embedded in the Code are the values of ASPS which are:

- surgical excellence and ethical practice
- honesty, integrity and respect
- compassion
- accountability
- scholarship and collegiality

These values guide us in our interactions with patients, fellow surgeons, trainees, nursing and allied health care staff, and other stakeholders in the health sector.

The practice of plastic surgery today encompasses a range of treatments, both surgical and non-surgical, particularly in the field of cosmetic medicine. This Code is intended to cover the full scope of practice undertaken by plastic surgeons, and should guide all their professional interactions with patients.

This Code of Practice was developed in response to member and community concerns in order to demonstrate that, as plastic surgeons, we hold ourselves to a clear set of ethical standards. The intention was to be patient-centred and focus on those aspects of professional behaviour that contribute to high quality patient care. ASPS was also concerned to create a transparent, enforceable and realistic compliance process based on a model of encouraging best practice by members.

The Code aims to provide a clear set of principles, in plain English, for the assistance of ASPS members. It sets out current standards and rules of behaviour, but is also intended to be a dynamic document that may be modified from time to time to reflect changing principles and obligations.

As plastic surgeons, we must comply with Federal and State laws as well as a range of rules and guidelines established by various bodies and statutory authorities such as: the Medical Board of Australia; State Health Departments; Consumer Affairs; the Therapeutic Goods Administration; the Australian Competition and Consumer Commission; Medicare; the Australian Medical Council; the Royal Australasian College of Surgeon (RACS); and the hospitals in which we work.

The ASPS Code of Practice does not replace or detract from any of the above. It is intended to sit alongside these other ethical and regulatory frameworks, and provide specific guidance on issues relevant to plastic surgery. It is therefore not an exhaustive ethical and professional code, and members will need to ensure that they comply with other relevant codes and guidelines as well.

Members must also be aware that some States have regulations that, in some areas, may be more restrictive than the principles set out in this Code. It is the responsibility of all members to familiarise themselves with applicable laws and regulations in their State.

General Principles

Members must demonstrate high standards of professionalism, integrity and ethical conduct in the practice of plastic surgery, and act at all times in the best interests of their patients.

They must strive to give effect to the values of ASPS which are:

- surgical excellence and ethical practice
- honesty and integrity
- respect for both patients and colleagues
- compassion
- accountability
- scholarship and collegiality

Members must at all times act in accordance with:

- the conduct required of them under Federal, State and Territory law and any Government rules or guidelines;
- all Codes and Guidelines of the Medical Board of Australia
- the Code of Conduct and other guidelines and standards of the Royal Australasian College of Surgeons; and
- the ethical and professional standards set out in this Code.

Members must ensure that they acquire and maintain the professional skills, experience and competence necessary to provide high quality care to their patients.

Members must respect the confidentiality of the information they hold about their patients.

Members must not engage in any activity which brings the practice of plastic surgery or ASPS into disrepute.

Members must conform to the codes and bylaws of the institutions in which they work.

1 Advertising

1.1 Members must familiarise themselves with the Guidelines for Advertising of Regulated Health Services issued by the Medical Board of Australia. A copy of the Guidelines is available from the Medical Board of Australia's website www.medicalboard.gov.au. These Guidelines set out detailed and specific requirements in relation to:

- What constitutes "advertising" by a medical practitioner;
- The substantiation of advertising claims;
- The responsibility of individual medical practitioners for the nature and content of any advertising relating to health services they provide;
- What kinds of statements or other information are acceptable in the advertising of health services;
- What kinds of statements of other information are unacceptable in the advertising of health services;
- The use of graphic or visual representations, such as "before and after" photos;
- The use of comparative advertising;
- Advertising of qualifications and titles;
- Advertising of price information;
- Offering gifts or discounts;
- The use of scientific information in advertising;
- Advertising of therapeutic goods, including scheduled medicines and vitamin supplements.

1.2 Members must be aware of the requirements of these Guidelines, and must ensure that they comply with them in every respect. A failure to comply with the Guidelines may constitute unprofessional conduct or professional misconduct on the part of the Member, as well as amounting to a breach of this Code.

2 Financial Arrangements

2.1 Members must make a full written disclosure to patients of what the cost of their treatment will be. The disclosure should be made at a sufficiently early stage to enable the patient to take cost considerations into account when deciding whether to undergo the treatment. The cost disclosure should include information about the possibility of further costs, should revision surgery be necessary.

2.2 Members must ensure that they do not have any financial conflict of interest that may influence their decisions and recommendations about patient care. The best interests of the patient must at all times be the paramount concern.

2.3 Members must disclose to patients any financial interest they have in any institution, company, arrangement or product related to any aspect of the patient's care.

2.4 Members must comply with the requirements of the Guidelines for Advertising of Regulated Health Services issued by the Medical Board of Australia in relation to the advertising of price information and the use of gifts or discounts in advertising.

2.5 Members must be careful to ensure that finance arrangements or financial incentives are not offered to patients in such a way that they may act as an inappropriate influence on a patient's decision as to whether the treatment is in his or her best interest. Examples of arrangements that are inappropriate include;

(a) giving a fee discount if the patient undergoes the surgery before a certain date;
(b) or offering other benefits, such as airfares, accommodation, spa treatment etc.; and
(c) entering into any arrangements with patients to assist them in obtaining finance to pay for a plastic surgery procedure, such as offering a credit facility (other than the use of a credit card), introducing the patient to a credit provider or providing information about possible loans.

2.6 Any bills rendered to patients by Trainees for work done assisting in the provision of plastic surgery services must be reasonable having regard to the Trainee's qualifications and level of experience. It is the responsibility of the individual Trainee to comply with relevant laws and guidelines in this respect, including obligations under employment contracts.

2.7 Members who use the services of Trainees outside the public hospital system should ensure, to the extent they are able to do so, that the Trainees receive appropriate payment for their work.

2.8 Members must not submit fee claims to any organisation, such as Medicare or WorkCover, unless they are satisfied that each claim is proper and meets the legal and other requirements of the relevant organisation.

3 Pre and Post-Operative Surgical Care

3.1 Members must take personal responsibility for ensuring that their patients are adequately informed of the nature of the proposed treatment, the likely post-operative course, and the possible risks, side-effects and complications. Wherever possible, the information should be provided in writing. Patients must receive this information at an early stage so they can make an informed decision about whether to agree to the treatment. They must be given sufficient time to consider the information, and have an opportunity to ask questions.

3.2 In a public hospital setting, members may sometimes rely on registrars or other medical staff to discuss the procedure with the patient and perform the pre-operative assessment. However, the plastic surgeon remains responsible for ensuring that the patient has been fully informed and adequately prepared for surgery.

3.3 Outside the public hospital setting, members must have an established relationship with the patient prior to undertaking any treatment. Members must personally conduct at least one pre-operative consultation with the patient and, unless the treatment is required urgently, the consultation must take place before the patient's admission to hospital. In most cases, and with all cosmetic surgery, at least two pre-operative consultations would be appropriate.

3.4 On-line consulting with a patient is not appropriate unless it is limited to the provision of general information about treatment options, and their potential risks and side-effects. No final diagnosis or recommendation for surgery should be made without a face-to-face consultation with the patient.

Cooling Off Period for Cosmetic Procedures

3.5 With cosmetic surgery procedures, it is particularly important that the patient is given sufficient time to think about whether the procedure is in his or her best interests. Members must ensure that there is a "cooling off" period of not less than ten days between the initial consultation with the patient and the cosmetic surgery procedure during which it must be made clear that the patient is free to withdraw from the procedure with no penalty. The patient must be told about the cooling off period prominently in writing.

3.6 Ideally, no deposit should be taken from the patient prior to the end of the cooling off period. If a deposit is taken, it should be fully refundable if the patient decides not to proceed with surgery.

Cosmetic Procedures for Patients under 18

3.7 Some States have specific rules to cover cosmetic procedures for patients under the age of 18. In Queensland, for example, it is unlawful to perform a cosmetic procedure on a patient under 18, while in New South Wales, there are special requirements for a "cooling off" period for these patients. Members must be aware of the law governing treatment for minors in their State or Territory. Even where cosmetic surgery is not specifically prohibited for patients under 18, members must exercise particular care when treating such patients to ensure that the treatment is in the patient's best interests and that legal requirements in relation to consent are satisfied.

Post-Operative Care

3.8 Members are responsible for ensuring that patients receive appropriate post-operative care and follow-up. If they cannot attend to this personally, they must make formal arrangements for the patient's post-operative care, and take steps to ensure that the patient, other treating health professionals and, if applicable, the clinic or hospital are made aware of these arrangements.

Itinerant Surgery

3.9 Members must exercise care when agreeing to perform itinerant surgery in a town or region that they visit for short periods only. While arrangements of this kind are sometimes in the best interests of patients, in that they increase the availability of specialist plastic surgery services, they carry inherent risks because the plastic surgeon may not be able to undertake necessary post-operative care and follow-up.

3.10 Members should only perform itinerant surgery if they have satisfied themselves that the local health facilities are adequate for the nature of the surgery to be undertaken and the local medical personnel have the necessary skills and experience to provide appropriate post-operative care. Arrangements must be in place for the emergency transfer of patients, if medically required.

Complications and Adverse Events

3.11 If a patient suffers an adverse event, or has an outcome that is less favourable than expected, members must provide the patient with an open and honest explanation of what has happened. There should be no attempt to cover up any complication or medical error.

3.12 Members must take responsibility for ensuring that the patient receives any further treatment required. They should seek a second opinion or refer the patient to another specialist, if this is in the best interests of the patient or if the patient requests it.

3.13 Revision surgery will sometimes be necessary even where there was no negligence or lack of skill or care in relation to the original surgery. This should be explained to the patient in advance. Where a patient requires revision surgery, members should take into account the out-of-pocket expense to the patient when determining the surgeon's fee for the revision surgery. If performing revision surgery on another surgeon's patient, members should be careful not to make inappropriate comments about the treatment provided by the previous surgeon.

4 Involvement of Non-Medically Qualified Personnel

4.1 While some members may wish to employ non-medically qualified personnel, such as nurses or beauty therapists, to assist with certain procedures, the responsibility for the patient's care rests with the member at all times. It is not acceptable to involve non-medically qualified personnel in the treatment of patients, unless these personnel are subject to an adequate level of supervision by the member.

4.2 Staff without medical qualifications who assist with patient care must clearly have the appropriate qualifications and training to do so.

4.3 Members must not allow non-medically qualified personnel to administer "prescription only" medication, unless the member has had a face-to-face consultation with the patient to determine whether the treatment is appropriate and has prescribed the medication.

5 Relationships with the Pharmaceutical and Medical Device Industries

5.1 Members must comply fully with the RACS Guidelines on Surgeons and Trainees Interactions with the Medical Industry. Members must also be aware of the Codes of Conduct of Medicines Australia and the Medical Technology Association of Australia which regulate advertising and promotional activities by industry. In relation to plastic surgery, in particular, the following provisions of the RACS Guidelines are relevant:

(a) Members must not accept financial remuneration, either by way of money or goods or services, based solely or partly on the use, or expectation of use, of medication, devices or prostheses.

(b) Members must not enter into any financial arrangement that could influence, or be reasonably expected to influence, the decisions they make on behalf of their patients. All such arrangements must be able to withstand public and professional scrutiny and conform to professional and community standards, ethics and expectations.

(c) Members must declare to the patient any arrangement with the medical industry that results in benefit, financial or non-financial, to the member, before any recommendations or decisions with respect to medication, prostheses, devices or technology on behalf of the patient are made.

(d) Except where they have been involved in the creation or development of a medical product, members must not promote or endorse a product other than by demonstrating or training others in the use of the product.

(e) Members must distance themselves from financial grants obtained from the medical industry. For example, educational grants should be directed to organising bodies, and payment for specific fellowship training should be by way of the specialist organisations.

(f) Members must not accept any financial support, direct or indirect, from the medical industry for attending educational meetings. The venue for such meetings should not be excessive or extravagant; the reason for a member deciding to attend should be the educational content, not the venue.

6 Use of the ASPS Name and Logo

6.1 Members must not act in a way that may bring ASPS or the practice of plastic surgery into disrepute.

6.2 Members must not hold themselves out as representing ASPS in any public forum or media communication, unless prior authorisation has been given by the President or Chief Executive.

6.3 Members may re-produce the ASPS logo on their stationery or in advertisements or promotional material for the sole purpose of communicating that they are a member of ASPS. Any other use of the logo is not permitted, except with the prior authorisation of the President or Chief Executive.

6.4 The ASPS name or logo should not be used alongside or in association with any sexually-provocative photos, or in any other way that might cause damage to the name or reputation of ASPS.

7 Mandatory Notification

7.1 Members must be aware of and comply with their obligation to report "notifiable conduct" on the part of another medical practitioner to the Australian Health Practitioner Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law Act 2009 and the Guidelines for Mandatory Notifications issued by the Medical Board of Australia. The obligation to report applies to certain types of serious misconduct, such as placing the public at risk of harm by reason of a significant departure from accepted professional standards, practising while intoxicated, or engaging in sexual misconduct.

7.2 Mandatory notification in these circumstances is a legal requirement that applies independently of this Code. Members who become aware of such behaviour on the part of another medical practitioner must report it to AHPRA.

8 Compliance with this Code

8.1 Upon becoming a member of ASPS and at the time of each annual renewal, members are required, as a condition of membership of ASPS, to sign a written acknowledgement that they:

(a) have read and agree to comply with:
  (i) all Codes and Guidelines of the Medical Board of Australia;
  (ii) the RACS Code of Conduct and other RACS standards and policies; and
  (iii) this Code of Practice.

(b) have complied with these Codes, Guidelines, standards and policies in their professional practice over the previous 12 months; and

(c) agree to submit to the RACS disciplinary procedure (see RACS Policy on Handling Potential Breaches) if a complaint is made against them and to be bound by the outcome of the procedure.

The written acknowledgment must be signed by all members of ASPS, including those who are not Fellows of RACS or not current financial members of RACS.

8.2 Any person may bring a complaint against a member of ASPS. Complaints must be in writing addressed to the Chief Executive of ASPS. Anonymous complaints will not be accepted.

8.3 The Chief Executive will refer any complaint received to the ASPS Ethics Committee. The Ethics Committee will review the complaint at its next meeting and do one or more of the following:

(a) if the complaint raises issues that may involve unprofessional conduct on the part of a member, a risk to patient safety, or a breach of any of the AHPRA Codes or Guidelines, refer the complaint to AHPRA (or in the case of some NSW complaints, the Medical Council of NSW) for investigation and determination under applicable legislation;

(b) in the case of any other complaint that warrants further substantive investigation, refer the complaint to RACS for investigation and determination under the RACS disciplinary procedure (see RACS Policy on Handling Potential Breaches);

(c) if the complaint raises issues that are sufficiently minor or straight-forward that the Ethics Committee considers it is able to deal with the complaint itself, deal with the complaint in accordance with paragraph 8.6 below; or

(d) if the complaint, in the opinion of the Ethics Committee, appears frivolous or vexatious, or does not raise issues of significance such as to warrant further investigation, dismiss the complaint and inform the complainant and the member to whom the complaint relates accordingly.

8.4 Where a complaint against a member is referred for further investigation under sub-paragraph 8.3(a) (b) above, the Ethics Committee will review the findings of the investigation, once concluded, and make recommendations to the Council of ASPS as to what action, if any, ASPS should take based on the findings of the investigation.

8.5 Where a complaint is referred to RACS for investigation and determination under paragraph 8.3(b), the decision of RACS will be final and binding, and the Council of ASPS will take whatever steps are necessary to give effect to the RACS decision.

8.6 If the Ethics Committee decides to deal with the complaint itself under paragraph 8.3(c) above, it will:

(a) inform the member in writing of the details of the complaint, provide a copy of the complaint and give the member 28 days within which to provide a written response to the complaint;

(b) undertake such further investigation of the complaint as the Ethics Committee, in its absolute discretion, considers appropriate;

(c) thereafter determine the complaint taking into account the matters contained in the complaint, the response received from the member and the results of the further investigation, if any, undertaken by the Ethics Committee;

(d) make recommendations to the Council of ASPS as to what action, if any, ASPS should take in response to the complaint.

8.7 Recommendations made by the Ethics Committee under paragraphs 8.4 or 8.6 above as to what action, if any, ASPS Council should take may include any or all of the following:

(a) dismissing the complaint;
(b) requiring the member to participate in counselling or other remedial programs;
(c) requiring the member to sign a statutory declaration stating that he or she will in future comply with this Code and other relevant Codes of Conduct;
(d) reprimanding the member;
(e) imposing conditions on the member's membership of ASPS;
(f) suspending the member's membership of ASPS for a specified period of time;
(g) expelling the member from ASPS.

8.8 When making its recommendation, the Ethics Committee must review any complaints previously made against the member and, where appropriate, take the complaints history into account. Where the member has already received two periods of suspension from ASPS within the previous five years, the Ethics Committee must bring this to the attention of the ASPS Council so that the Council can consider whether to expel the member from ASPS.

8.9 The Council of ASPS will consider the recommendations of the Ethics Committee at its next meeting and will decide what action, if any, should be taken in response to the complaint. The Council will write to the member and the complainant informing them of its decision.

8.10 Any decision by the Council of ASPS to reprimand, impose conditions on, suspend or expel a member will be published on the public domain of the ASPS website.

Version: 1
Approved: 25 November 2011
Review: November 2012

Schedule of Legislation

This Schedule of relevant legislation in each State and Territory is provided to assist members to identify laws that may be relevant to their professional practice. The schedule is not necessarily exhaustive, and members may need to seek legal advice from their medical defence organisation or elsewhere in order to ensure they have an accurate and up-to-date understanding of their legal obligations.

Commonwealth
Privacy Act 1988 (Cth)
Therapeutic Goods Act 1989 (Cth)
Trade Practices Act 1974 (Cth)
National Consumer Credit Protection Act 2009 (Cth)

New South Wales
Fair Trading Act 1987 (NSW)
Health Practitioner Regulation National Law (NSW)
Health Care Complaints Commission Act 1993 (NSW)
Health Records and Information Privacy Act 2002 (NSW)
Privacy and Personal Information Protection Act 1998 (NSW)

Queensland
Fair Trading Act 1989 (Qld)
Health Practitioner National Law Act 2009 (Qld)
Health Practitioners (Professional Standards) Act 1999 (Qld)
Health Quality and Complaints Commission Act 2006 (Qld)
Information Privacy Act 2009 (Qld)
Medical Practitioners Registration Act 2001 (Qld)
Public Health Act 2005 (Qld)

South Australia
Fair Trading Act 1987 (SA)
Health and Community Services Complaints Act 2004 (SA)
Health Practitioners Regulation National Law (South Australia) Act 2010 (SA)

Tasmania
Fair Trading Act 1990 (Tas)
Health Complaints Act 1995 (Tas)
Health Practitioner Regulation (National Law) Act 2010 (Tas)

Victoria
Fair Trading Act 1999 (Vic)
Health Practitioner Regulation National Law (Victoria) Act 2009 (Vic)
Health Records Act 2001 (Vic)
Health Services (Conciliation and Review) Act 1987 (Vic)
Health Professions Registration Act 2005 (Vic)

Western Australia
Fair Trading Act 1987 (WA)
Health Services (Conciliation and Review) Act 1995 (WA)
Medical Practitioners Act 2008 (WA)

Australian Capital Territory
Fair Trading Act 1992 (ACT)
Health Practitioner Regulation National Law (ACT) Act 2010 (ACT)
Health Professionals Act 2004 (ACT)
Health Records (Privacy and Access) Act 1997 (ACT)

Northern Territory
Consumer Affairs and Fair Trading Act 1990 (NT)
Health Practitioner Regulation (National Uniform Legislation) Act 2010 (NT)
Health Practitioners Act 2004 (NT)
Health and Community Services Complaints Act 1998 (NT)

Australian Society *of* Plastic Surgeons

AUSTRALIAN SOCIETY OF PLASTIC SURGEONS INC
MEMBER'S ANNUAL DECLARATION

I, _____ declare as a condition of membership
(Print name)
of the Australian Society of Plastic Surgeons Inc (ASPS) that I:

(a) Have read and agree to comply with:
   (i) all Codes and Guidelines of the Medical Board of Australia;
   (ii) the RACS Code of Conduct and other RACS standards and policies; and
   (iii) the ASPS Code of Practice.

(b) Have complied with these Codes, Guidelines, standards and policies in my professional practice over the previous 12 months; and

(c) Agree to submit to the RACS disciplinary procedure (see RACS Policy on Handling Potential Breaches) if a complaint is made against me and to be bound by the outcome of the procedure.

DATE: ____/____/20____

Signature: _____

Please return this declaration to ASPS office with your annual subscription renewal to:

Membership Secretary
Australian Society of Plastic Surgeons Inc.
Suite 503, Level 5, 69 Christie Street
St Leonards NSW 2065

Australian Society of Plastic Surgeons

Recommendation on the Proposed Management of Patients with PIP Breast Implants

25 January 2012

Author:
Assoc. Professor Rodney Cooter MB. BS., MD (Adel), FRACS
ASPS President

Disclaimers:

- These recommendations are made as at the date of this document and based on evidence available at the time.
- ASPS may review these recommendations in the future.
- This guidance is of a general nature and not tailored to an individual person's needs**.**
- Patients should seek medical advice tailored to their circumstances from their treating doctors.

Summary

The Australian Society of Plastic Surgeons (ASPS) recommends the removal of all PIP breast implants from Australian patients by the end of 2014. In March 2012 it will be 2 years since the last PIP breast implant was inserted in Australia.

As at 17 January 2012, the available data from batch testing of PIP breast implants by the Therapeutic Goods Administration has not revealed any toxic substances in the gels or any abnormal weaknesses in the implant shells. There are no compelling clinical datasets to warrant a more urgent call to remove these devices but in the event of more conclusively negative findings, ASPS will recommend shorter time frames for a proposed explant strategy. Equally, if more solid data supporting the safety of PIP implants becomes available then longer time frames for explantation could be appropriate.

Importantly there is no international consensus about the recommended lifespan of breast implants. Many clinicians recommend replacement at 10 years post-implantation because all implants have a minimal rupture rate of approximately 1%-1.3% per annum, hence at least 10%-13% will be ruptured at 10 years. Taking into consideration the performance profile of normal implants and the uncertainties about the PIP implants, ASPS recommends removal of all PIP devices within 5 years of their insertion: as almost 2 years has already elapsed since the last insertion, the explantation program will be complete within the next 3 years.

Priority will be given to those patients with known implant ruptures, and to those patients who have had PIP implants as part of a post-mastectomy breast reconstruction program, and those with implants inserted over 5 years ago.

Mission of the Australian Society of Plastic Surgeons

The Australian Society of Plastic Surgeons (ASPS) aims to maintain the highest standard of surgical practice and ethics in Plastic Surgery in Australia in order to provide the highest quality plastic surgery care to all Australians.

The recommendations made in the report have been formulated by a panel of 14 members including the full Council of ASPS and ex-officio members: the Chairman of the Board of Plastic Surgery, the Vice President of the Royal Australasian College of Surgeons, the Vice President of the Australasian Society of Aesthetic Plastic Surgery, the ASPS Younger Fellows Representative, the ASPS Trainee Representative as well as ASPS executive administration. Of the 14 member consultative group, representatives were from 5 Australian states including NSW, Vic, SA and WA. None of the 14 member group had any conflict of interest in the recommendations proposed.

Background to the Australian PIP Breast Implant Problem

In making recommendations about the management of patients with PIP implants ASPS has assessed the existing data and the recommendations of other countries. There is much uncertainty and a significant lack of solid data. Importantly, there is no known link to cancer.

Popular press is driving the issue into the conscious mind of the general public here and overseas. There appears to be a growing expectation in the general community that government must act. For this reason, the "References" section in this paper, unusually, includes media articles such as the Observer's piece on 8 January: "Out of a scandal must come proper regulation"[1] and the Reuters' piece on 10 January: "The troubled history of PIP's implants man in America".[2]

PIP implants had been available in Australia since 1998 from Precise Medical until 2004; Medical Vision then became the agent for distribution in Australia until March 2010 when French authorities discovered non-medical grade silicone was being used in PIP implant manufacture. In April 2010 all unused Australian PIP implants were recalled and an immediate ban placed on their use. Testing of PIP stocks by the Therapeutic Goods Administration (TGA) failed to identify any abnormalities in the tensile strengths of the implant shells nor any toxic components in their internal gels. While many anecdotal reports of an increased rupture rate of PIP implants have emerged there is no statistical evidence to support those assertions. Similarly claims have emerged of toxic compounds being identified in the PIP implant gels but none have been identified in gels tested by the TGA. It is unclear whether any of the PIP implants with faulty gels were sold in Australia.

While no hard data exist, the well documented explantation programs proposed in countries such as France, Germany, Czech Republic and Wales, to name a few, have only served to heighten the anxieties of Australian patients with these breast implants. Indeed the situation has been further compounded by the International Society of Aesthetic Plastic Surgery (ISAPS), the largest society of international plastic surgeons (2100 members in 93 countries) announcing on its web site that it strongly supports the removal of PIP implants, even if they are not ruptured.[3]

The lack of a comprehensive, prospectively gathered registry dataset in any of the countries involved nor from any of the international plastic surgical societies has severely compromised the formulation of management guidelines for patients with these devices. Many countries including Australia had set up Breast Implant Registries (BIR) following the Dow Corning silicone breast implant class action suit

in the early 1990s. These were 'opt-in' registries which have since proved of little value because of their voluntary nature and low capture rates. Some were abandoned through poor design. Australia's BIR has been maintained since 1998 and has parliamentary privilege.[4] It too has suffered from the same flaws as other countries' 'opt-in' registries as a result of very low capture rates. The PIP situation has been the first opportunity to validate the Australia BIR data; in the knowledge that 12, 341 PIP implants were sold, the BIR captured less than 5% of these. Not only was the registry's 'opt-in' design at fault but each patient was levied a fee to be included in the BIR thereby compounding the disincentives to participate.

Known Facts

Ruptures

Most breast implants will eventually rupture; in general terms implants will last about 10 years with a low rupture rate of 1%-1.3% per year.[5] Between 11 and 20 years most will rupture and after 20 years few will still be intact.[6] Significantly high rupture rates of these devices has been known for many years with 20% ten year rupture rate and 50% 15 year rupture rates reported in 1998.[7]

Imaging

To monitor breast implants, MRI is highly accurate in identifying ruptures with high sensitivity and specificity.[8,9] The imaging of choice for "standard" international practice for assessment of breast implant integrity is MRI. The study is non-invasive, does not involve an injection, and takes approximately 25 minutes to perform. The MRI allows for assessment of implant rupture and peri-implant complications. The results will assist in surgical explant. Technological infrastructure of magnet and dedicated breast coil are required at sites performing MRI.[10]

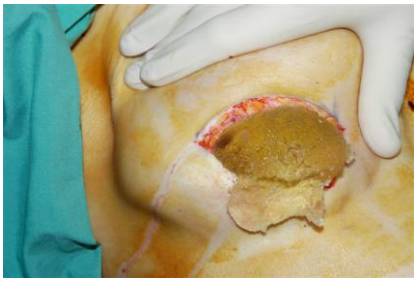
Explantation

The governments of several countries are planning mass explantation surgical programs; priority will be given to cancer patients with implant based reconstructions with regard to re-implantation. The UK government has offered a selective explantation program for those patients who were managed under their National Health Scheme but not the bulk of those patients who had PIP implants inserted privately. This decision has generated a degree of uncertainty "as patients are feeling more confused and anxious now than ever before. With current Government position remaining unclear, patients want to know the timeline for the further investigations into PIP implants".[11]

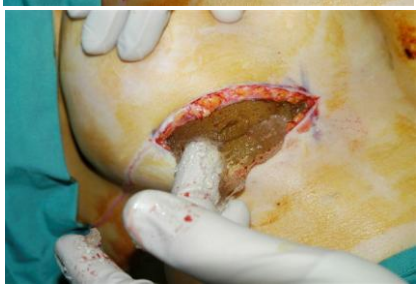
Anxiety

The level of patient anxiety in this situation must be closely considered. Seemingly conflictual reports from other countries and unclear guidelines will only serve to increase the anxiety of patients who received PIP implants in good faith with the assumption they were manufactured to rigorous standards.[12] This is a worrying time for patients.[13]

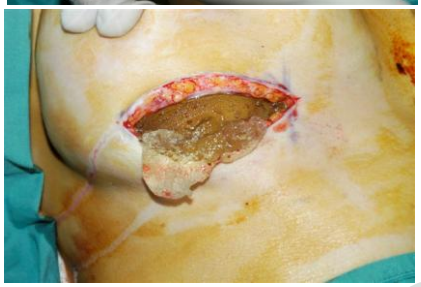
a)



b)

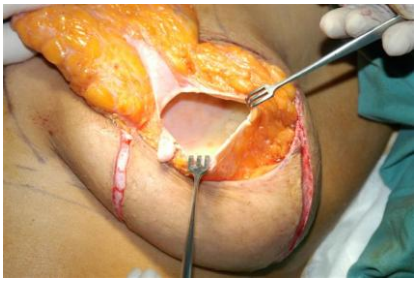


c)

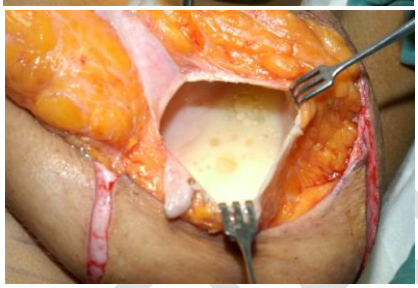


Figures 1(a-c):Typical ruptured non-PIP implant – no milky fluid component
Implanted 2004 ;Explanted 2011

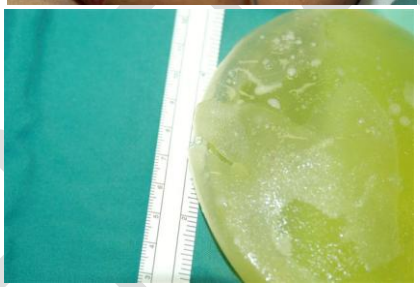
a)



b)

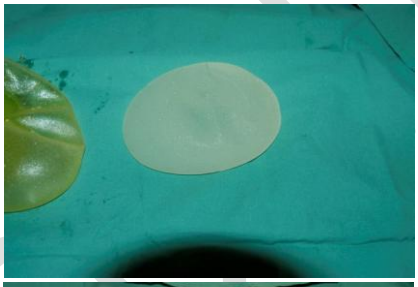


c)



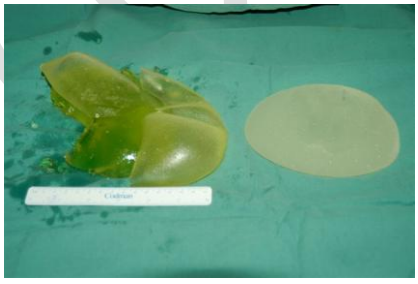
Figures 2(a-c): Ruptured PIP breast implant demonstrating oily suspension intracapsular
Implanted 2005 ; Explanted 2012

a)



b)

c)



Figures 3(a-c): Ruptured PIP Breast Implant. Implanted 2003; Explanted 2006

Assumptions

A consequence of a lack of solid data, such as Level 1 or 2 evidence, is that assumptions must be made based on clinical experience, and anecdotal reports from local, national and international colleagues; at best Level 4 or 5 evidence.[14]

Assumption 1: Ratio of Cosmetic: Reconstructive patients = 80: 20
i.e. of the approximately 12,500 implants 10,000 would be cosmetic and 2,500 would be reconstructive.

Assumption 2: Industry standard silicone implant rupture rates are 10%-13% at 10 years.[5]

Assumption 3: If a PIP implant has an extra-capsular rupture, its removal is strongly recommended as soon as practicable. (An extra-capsular rupture refers to the migration of silicone beyond the fibrous layer, or capsule, around the implant.)

Assumption 4: If a PIP implant has an intra-capsular rupture, its removal is recommended on a non-urgent basis. (An intra-capsular rupture means that silicone gel has escaped from the implant shell but has been contained within the fibrous layer, or capsule, around the implant.)

Assumption 5: Implants for reconstruction have higher complication rates than implants for cosmesis.

Assumption 6: If a PIP implant has been used to reconstruct a breast after a mastectomy for breast cancer, it should be removed and an alternative implant inserted.

Assumption 7: A PIP implant that is demonstrated intact on MRI can be safely monitored clinically and with serial MRIs. (MRI is magnetic resonance imaging and does not involve harmful xrays.)

Unknown Factors

It is unknown if faulty gel was used in PIP implants imported into Australia (none have been identified by TGA testing to date);

It is unknown if the actual rupture rate of PIP implants is different to other comparable devices (there is much anecdote written about increased rupture rates but little hard evidence);

It is unknown if a PIP implant rupture can be accurately determined using clinical examination alone unless there is obvious deformation;

It is unknown if the implanted life of a PIP implant is as long as expected of other implants (approximately 10 years).

Recommendations

In view of the limited lifespan of all implantable devices and the reasonable lifespan of 10 years for highly quality silicone breast implants, it is logical to recommend removal of "time expired" devices. With the foregoing 'Background', 'Known facts', 'Assumptions' and 'Unknown facts' in mind and with due respect for the anxiety levels of our PIP patient populations it is the recommendation of ASPS that an explantation program be coordinated by the Federal Department of Health and Ageing in a timely manner. This is in accordance with the strong recommendation of ISAPS that PIP implants should be removed even if they are intact.

Given that it is almost 2 years since the last PIP implant was inserted, and that much uncertainty surrounds the PIP implant performance in situ, ASPS recommends the explantation of all PIP implants that have been in place for more than 5 years. This plan will therefore see the explantation of all PIP implants within the next 3 years.

A gradual sequence of explantation is envisaged with priority given to patients with 5 year old implants, patients with unresolved anxiety, breast cancer patients and those too claustrophobic for MRI examination.

To achieve this explantation program in a timely organised fashion, ASPS has made 3 levels of recommendations as follows:

1. Strongly recommended: covers prioritisation of patients, MRI monitoring data capture, new Registry and funding.

2. Recommended: expedites the relevant explants, patient item numbers, MRI item numbers and patient co-payment strategy.

3. Preferred: consideration of wider issues with longer time frames.

A clinical map has been devised and an example data collection form proffered to gather all information into a central repository. Clinical and radiological guidelines will also form part of the suite of recommendations.

The above recommendations in detail:

1. Strongly Recommended:

   i. All PIP breast implant patients should be clinically examined by their surgeon after referral from their general practitioner. This review will establish the date and details of their implant surgery.

   ii. Patients will be prioritised into 3 groups:
   - Explantation as soon as possible if evidence of extra capsular rupture from MRI examination.

- Non-urgent explantation if evidence of an intra capsular rupture from MRI, or also if implants have been in place for 5 or more years, or if the patient has anxiety not alleviated by reassurance, or if claustrophobic and unable to have an MRI, and if a breast cancer patient with a PIP implant used for post mastectomy reconstruction.
- Monitoring until 5 years post implantation with clinical and/or radiological examinations on a 6 month basis for surgeon review or an "as needs" basis for general practitioner review.

iii. A Government funded opt-out or compulsory Breast Device Registry, to capture all future implanted breast device data, to be established forthwith.[15] (Refer Appendix 1 for example of data capture form for new Breast Device Registry)

2. Recommended:

i. A clinico-radiological Technical Reference Group be established to assist the Chief Medical Officer to facilitate this program of assessment and explantation. The group would comprise experienced clinicians and researchers to gather all PIP data into a central repository for analysis. Such a coordinated approach would collate clinical, radiological, surgical and post-explant device testing data. The cohort of PIP patients would be monitored post-explantation for untoward clinical outcomes.

ii. Breast cancer patients to have their breast reconstruction implants replaced with an alternative device at no personal expense.

iii. Medicare Item Numbers to be made available for the 3 year explants period and only available for use if patient and surgeon are enrolled into the explant program. A separate set of Item Numbers to those currently used could be employed but with the suffix "P" e.g. "45552P" to clarify the purpose of that number. This distinction is particularly relevant to distinguish these cases from related procedures.

iv. Replacement of alternative breast implants for patients with cosmetic augmentation to be covered by Item Numbers 45553P or 45554P or 4555P if privately insured. Negotiations will be required with private heath funds. Uninsured patients will have a co-payment requirement to fund new implants. Their explant surgery alone to be covered by numbers 45548P or 45551P. (Refer Appendix 2) A theatre and operating fee payment mechanism will be required for uninsured patients.

v. MRI examinations of breast implants to be funded by both Medicare and the patient. A nationally agreed level of reimbursement to be negotiated with radiologists, A guide could be the current reimbursement of MRI breast parenchyma examination item numbers 63464P or 63467P (Refer Appendix 2)

3. Preferred:

   i. Standardized MRI protocol to be established with all digitised data reviewed by members of the Chief Medical Officer's clinico-radiological reference group.

   ii. Six monthly MRIs if indicated after clinical assessments.

   iii. Implant surgeon to be explant surgeon. If implant surgeon not available or no longer in practice then ASPS will assist the Department of Health and Ageing by providing a list of available specialist plastic surgeons..

   iv. All explanted devices to have minimal testing to assess gel toxicity.

   v. Clinico-radiological reference group to publish outcomes of the explants program in international medical literature.

   vi. Promotion and sharing of the new opt-out Breast Device Registry design and datasets with international clinical colleagues and government agencies to facilitate internationally comparable data.

   vii. Clearer reporting and communication channels to and from the TGA for patients and clinicians.

   viii. Tighter control by the Australian Medical Board of website and media advertising of cosmetic surgery to reduce the risk of patient confusion and unrealistic expectations.

General Practitioner Clinical Review

- assess patient generally, comorbidities
- any specific breast symptoms or signs
- age of implants
- level of patient anxiety
- referral to implanting surgeon or alternate
- radiology eg. ultrasound, MMG if breast parenchyma concern
- MRI if specific implant rupture concerns

Surgical Review

History

- patient demographics - name, date of birth, address, contact details, contact person,
- medicare number - private insurance details
- date(s) of implant insertion
- implant: i……/ plane/ size/ shape/ surface texture / lot number/ serial number
    - reason for implants - cosmetic
      - asymmetry
      - cancer reconstruction
    - current implant issues - pain
      - asymmetry
      - hardening
      - shape change
- anxiety level
- breast cancer history - breast imaging
  - dates : MMG_____
    : U/S _____
    : MRI _____
  - findings_____
- other surgery
- anaesthetic issues
- mediations
- allergies
- smoking history

Examination

- Appearance -normal
  -asymmetry
  -ptosis
  -scar quality
  -scar site
  -breast animation with pectoral muscle
  -contractions
  -skin erythema

- Measurement -SN – N right_____ left_____
  -N – IMC right_____left_____
  -breast width right_____ left_____
  -superior pole pinch thickness
  right_____ left_____
- Palpation -breast lumps
  -axillary lymphadenopathy
  -Baker's capsular
  contracture score right_____left_____

- Photography -front upright

-lateral right and left
-oblique right and left
- bird's eye supine
-worm's eye

- Investigations -MMG
-U/S
-CT
-MRI

- Breast Device Registry (BDR) Enrolment Yes No

  * An example of a BDR data form is in Appendix 1

Radiology Review [16]

1. The benefit of implant MRI over implant Ultrasound:

Implant MRI:

- MRI is well recognised as the "gold" standard for implant imaging.
- MRI is highly sensitive and specific for assessment of implant rupture. It allows comment upon whether the rupture is contained within the capsule or has spread beyond the capsule into the breast tissue and beyond into the lymphatics with silicone in lymph nodes.
  (characterised as extra capsular, intracapsular, free parenchymal silicone and silicone adenopathy)
- The approximate dimensions of the amount of ruptured silicone within the breast tissue can be measured, as can where it lies in the breast assisting in its surgical removal.
- MRI allows assessment of the entire implant and any collection of fluid around the implant and what type of fluid it is.
- MRI is not limited by breast density, size of breast.

Ultrasound:

- Ultrasound is less sensitive and specific in the detection of implant rupture, limited to the type of implant rupture where silicone spreads beyond the capsule into the breast tissue and where there is fluid anterior to the implant, and where there is gross silicone replacement of lymph nodes.

  However Ultrasound does have several **limitations** and these include –
- Ultrasound (sound waves) cannot easily penetrate through the implant and so anything occurring within or posterior to the implant, either rupture or collection cannot be accurately or reliably detected. (*MRI shows entire implant)
- Thus contained rupture cannot be reliably diagnosed on ultrasound, and this includes the varying grades of intracapsular rupture, (cases of intracapsular rupture will inevitably progress to extracapsular rupture in most cases and so the presence of this may indicate surgical explantation.)* this a strong benefit of MRI.
- Fluid around the implant often collects posterior to implant, and this is a blind area on ultrasound (*well seen on MRI)
- Subtle silicone within lymph nodes will not be seen on ultrasound (ie. appear normal), whereas does show up easily on *MRI.

2. Comparison of technique of Implant MRI versus Ultrasound versus Screening cancer MRI:

- **Implant MRI:** 25 minute procedure then with radiologist reporting time variable depending upon complexity of case. No IV injection/non-invasive procedure.
  Operator/reader easily managed, as imaging is digital and can be sent via computer anywhere in country or world via internet to be interpreted by radiologist (privileged and confidential files). Small group of reporting radiologists recommended to allow uniformity and consistency in reports. Research proposal possible and international links for highly skilled implant radiologists available for co-reporting.

- **Implant/Breast Ultrasound:** 60 minute procedure with imaging/scanning performed by radiographer, then films interpreted and reported by radiologist.
  Time poor study and very operator dependant – difficult to control skill level across many locations. Ultrasound is well known to be a "real time" investigation, so not auditable and difficult to maintain uniformity in technique of scanning and assessment and interpretation.
- **Breast cancer screening MRI**: 30 minute procedure then with radiologist reporting time variable depending upon complexity of case.

3. Cost Analysis of Implant MRI:

There is a presumption of technology infrastructure at the site where breast MRI imaging is performed and this requires a dedicated breast coil of 7 or 8 channel on a 3T or 1.5T magnet and high resolution computers for viewing images (require 5MP monitors where mammograms are done).
This equipment comes at a high cost to the infrastructure of the department performing quality breast imaging, and in association with the time intensive nature of reporting at a high skill level, explains the high costs associated with breast imaging.

Given the comparable imaging requirements of the infrastructure of the magnet and dedicated breast coil, with similar procedure times and reporting times and with specific skill requirements in such a field, the current breast MRI screening items numbers (63464 and 63467) are felt to be an appropriate recompense for implant MRI.

It is important that no gap payment is encouraged.

A proposed MRI reporting template is provided below:

PIP Reader Form document Proposal

Reader 1

Reader 2

Reader 3

Study Date

RIGHT:

Sequences performed:

1. optimal
2. adequate
3. partially adequate
4. inadequate
5. completely unsatisfactory

Image Quality:

1. very high
2. good
3. adequate
4. conveys information, inadequate for purpose
5. completely inadequate

Implant Placement:

Subglandular

Subpectoral

Rupture:

No evidence

Indeterminate

Uncollapsed rupture

Minimally collapsed rupture

Partially collapsed rupture

Fully collapsed rupture

Soft Tissue Silicone in breast:

Nil

Possible

Probable

Definite

Amount- cc

Maximum distance from implant- mm

Silicone Adenopathy:

Present/absent – axillary nodes

Present/absent – Internal mammary chain nodes

Peri-Implant Fluid:

Nil

Trace

More than usual

Septations present/absent in fluid

Additional Findings:

LEFT

Sequences performed:

6. optimal
7. adequate
8. partially adequate
9. inadequate
10. completely unsatisfactory

Image Quality:

6. very high
7. good
8. adequate
9. conveys information, inadequate for purpose
10. completely inadequate

Implant Placement:

Subglandular

Subpectoral

Rupture:

No evidence

Indeterminate

Uncollapsed rupture

Minimally collapsed rupture

Partially collapsed rupture

Fully collapsed rupture

Soft Tissue Silicone in breast:

Nil

Possible

Probable

Definite

Amount- cc

Maximum distance from implant- mm

Silicone Adenopathy:

Present/absent – axillary nodes

Present/absent – Internal mammary chain nodes

Peri-Implant Fluid:

Nil

Trace

More than usual

Septations present/absent in fluid

Additional Findings:

Consideration of Implications of ASPS Recommendations

For Patients:

To do nothing but monitor the situation would be unacceptable to patients due to the uncertainty of so many factors and the anxiety engendered by that doubt. To shorten the time frame of the proposed 3 years of explant strategy may serve to increase patient anxiety and with appropriate patient prioritisation all will be treated fairly. To lengthen the time frame would be too long for anxious patients to wait and would involve increased monitoring. The patient prioritisation process is a guide and any patient's priority could be altered anytime, hence regular GP reviews on an "as needs" basis and at least 6 monthly surgical reviews until explantation.

Rationale for patient prioritisations:
Extra capsular rupture – removal of the implant as soon as practicable is warranted to avert the further migration of silicone to lymph nodes and to other remote tissues.

Intra capsular rupture – non urgent removal is appropriate because the silicone is contained within the fibrous capsule surrounding the implant. Non urgent cases could be added to the next available elective list, within 3 months.

Consideration of Implications of ASPS Recommendations:
Claustrophobia – some patients may not tolerate the noise and close confines of an MRI scanner.
Unresolved Anxiety – difficult to measure objectively but could be a leading factor since patients had these devices inserted in good faith that they were safe.

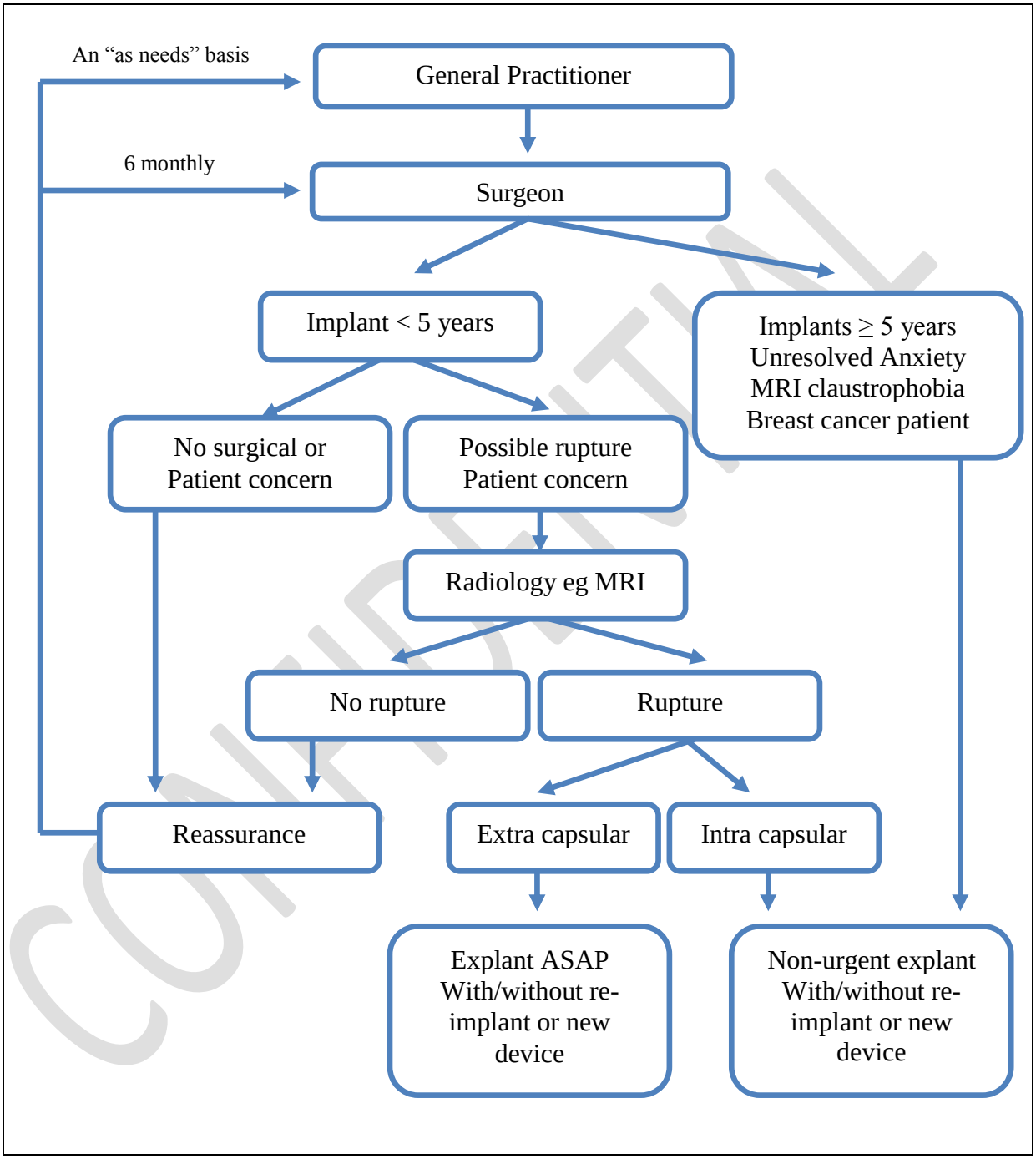
For Medicare and Health Funds:

Clinical Assessments	Usual Medicare consultation numbers should apply
MRI	A new Item Number is required, on a temporary basis to reimburse radiology group. A co-payment or levy from the patient e.g. $100-$200 may be reasonable.
Surgery	Temporary surgical numbers for the 3 year program could be used only by surgeons registered in the explants program. (Appendix 2)
	Suffix "P" to Item Number will make monitoring of these codes much more streamlined and allow health economists to establish financial mapping of this program. (Appendix 2)
	Private Health Funds will need to be consulted and levels of reimbursement established for PIP patients with private insurance.

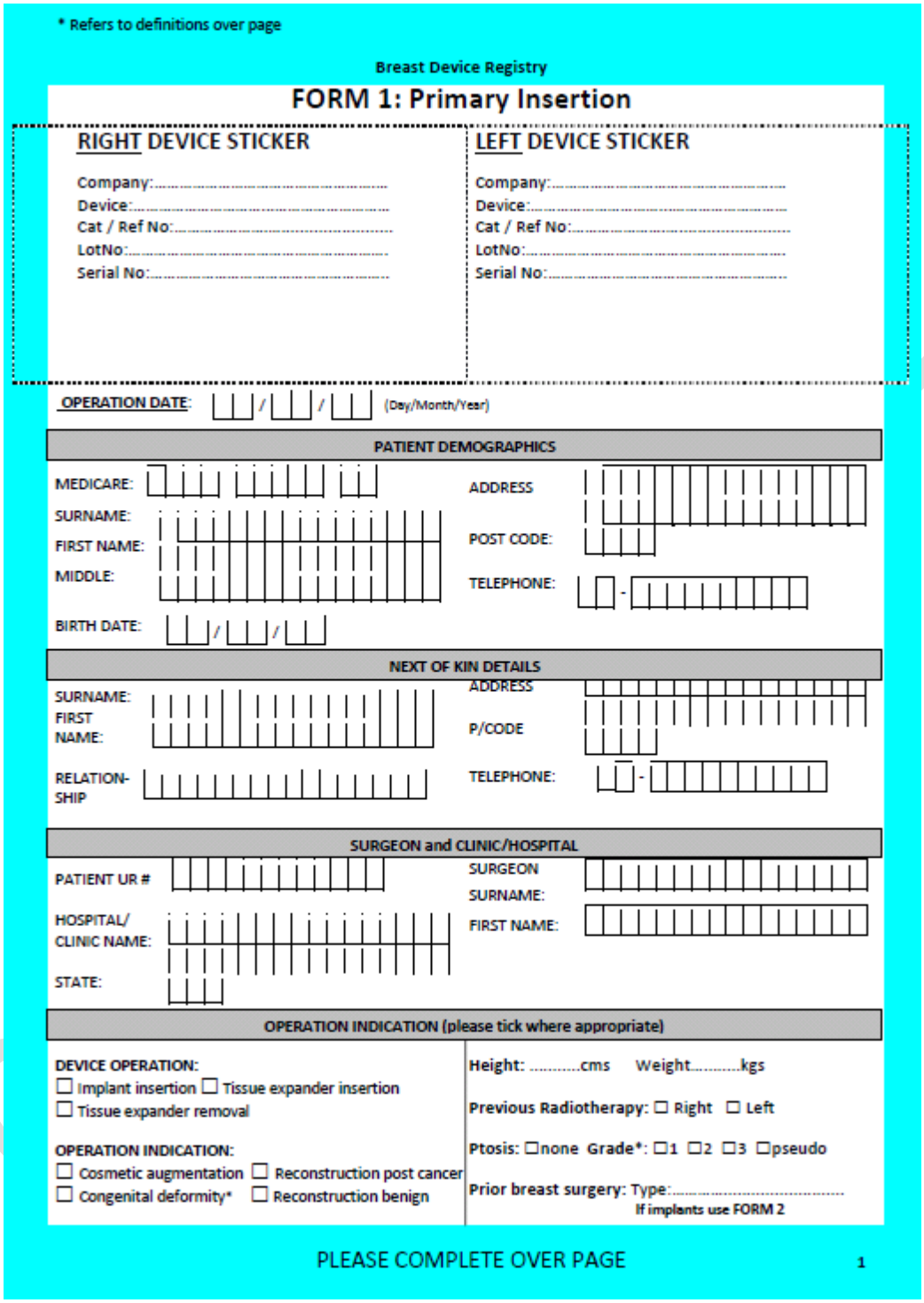
	Hospital and Day Surgery theatre fees and facility fee structures will need examining for uninsured patients who will likely incur a co-payment if government funding is not provided. Anaesthetist and Assistant fee structures will also need to be determined.
Surgical Complications	All surgery has risk and potential complications and costs will be incurred in their management.
<u>For Surgeons:</u>	
Medical Defence Insurance	Indemnity issues will need to be clarified before embarking on a major explantation program.
Ongoing Implant Work	In addition to considering the stress on surgical theatre times, existing workloads must be maintained. [17] (Appendix 3)
Explantation risks	There are many risks and potential complications with this type of surgery. They include all associated anaesthetic risks, general risks of any surgical intervention such as scarring, bleeding, infection and thrombo embolism as well as specific implant surgical risks such as a compromised aesthetic result, damage to anatomical structures that may result in such outcomes as loss of nipple/areola sensation, removal of breast tissue adherent to the implant capsule, pneumothorax, pain, dysesthesia.
Entrepreneurial risks	If funding is made available for an explant program it is imperative that the funds are linked by early identifiable Item Numbers and surgeon and patient enrolment to off-set the risk of inappropriate or abusive financial activity by unscrupulous operators.
Informed Consent	A comprehensive information sheet needs to be provided to all PIP patients enrolled in the explant program; this should be standardized for all surgeons and patients and have the imprimatur of Government, the Royal Australasian College of Surgeons and Medical Defence Organisations.
Own risk opt-out	Some patients with PIP implants may choose not to enrol in the explant program and will therefore be required to sign an “Own Risk Against Medical Advice” document.

RECOMMENDATION:

Clinical Map for the Proposed Management of PIP Breast Implant Patients



Appendix 1. An example of a Breast Device Registry data form.



* Refers to definitions over page

Breast Device Registry

FORM 1: Primary Insertion

RIGHT DEVICE STICKER

Company:
Device:
Cat / Ref No:
LotNo:
Serial No:

LEFT DEVICE STICKER

Company:
Device:
Cat / Ref No:
LotNo:
Serial No:

OPERATION DATE: / / (Day/Month/Year)

PATIENT DEMOGRAPHICS

MEDICARE:
SURNAME:
FIRST NAME:
MIDDLE:
BIRTH DATE: / /
ADDRESS
POST CODE:
TELEPHONE:

NEXT OF KIN DETAILS

SURNAME:
FIRST NAME:
RELATION-SHIP
ADDRESS
P/CODE
TELEPHONE:

SURGEON and CLINIC/HOSPITAL

PATIENT UR #
HOSPITAL/ CLINIC NAME:
STATE:
SURGEON SURNAME:
FIRST NAME:

OPERATION INDICATION (please tick where appropriate)

DEVICE OPERATION:
☐ Implant insertion ☐ Tissue expander insertion
☐ Tissue expander removal

OPERATION INDICATION:
☐ Cosmetic augmentation ☐ Reconstruction post cancer
☐ Congenital deformity* ☐ Reconstruction benign

Height: .....cms Weight.....kgs

Previous Radiotherapy: ☐ Right ☐ Left

Ptosis: ☐none Grade*: ☐1 ☐2 ☐3 ☐pseudo

Prior breast surgery: Type:.....
If implants use FORM 2

PLEASE COMPLETE OVER PAGE 1

FRONT OF BDR DATA FORM FOR PRIMARY INSERTION

* Refers to definitions over page

OPERATION DETAILS

Incision*:

Infra-mammary	☐ Right	☐ Left
Mastectomy scar	☐ Right	☐ Left
Axillary	☐ Right	☐ Left
Areolar	☐ Right	☐ Left
Other	☐ Right	☐ Left

Additional Elements of Operation

Mastectomy	☐ Right	☐ Left
Mastopexy (<100g)	☐ Right	☐ Left
Reduction (>100g)	☐ Right	☐ Left
Flap cover	☐ Right	☐ Left
Mesh or dermal sheet	☐ Right	☐ Left

Tissue Expander Intra operative **Fill volume:**
RIGHT:_____mls LEFT:_____mls

Plane*:

Subglandular:	☐ Right	☐ Left
Sub pectoral	☐ Right	☐ Left
Sub fascial	☐ Right	☐ Left
Dual plane	☐ Right	☐ Left

If Dual plane please circle 1, 2, or 3 below:
1. IMF muscle division
2. Subglandular to NAC inferior border
3. Up to NAC level superior border

Insertion Technique & Antibiotics

☐ Antiseptic rinse ☐ Systemic Antibiotics
☐ Post-op Antibiotics ☐ Antibiotic solution
☐ Skin barrier protector* ☐ Glove change for insertion

Drains: ☐ Via wound ☐ Via Skin ☐ Suction

Definitions

Areola: Around the lower border of the nipple/areola
Axillary: Through the armpit
Capsulectomy full: complete removal of capsule
Capsulectomy partial: is surgically released and/or partially removed through an incision within the breast area.
Baker classification of capsular contracture
Grade I: breast is soft with no palpable capsule & looks natural;
Grade II: breast is slightly firm, with a palpable capsule & looks natural
Grade III (moderate): the breast is firm with an easily palpable capsule and looks abnormal;
Grade IV (severe): the breast is hard, cold, painful, and distorted
Dual Plane: The implant placed under the superior portion of the pectoralis major muscle; inferiorly, the implant is placed in a subglandular plane.
Infra-mammary: In the fold under the breast
Mastectomy: Via the mastectomy scar
Primary Operation: Any previous permanent breast implant surgery
Ptosis: Pseudo: Nipple is normal level but breast has slid down below level of breast crease giving appearance of bottomed-out breast.
Grade 1 nipple is the level of the breast crease
Grade 2: nipples have dropped below level of breast crease, but higher than majority of breast
Grade 3: nipples below breast crease at level of maximum projection
Skin barrier protector: such as funnel/skin adhesive film over incision
Subglandular: Beneath the gland and above the muscular fascia
Sub fascial: Above implant pectoralis muscle but below the pectoralis fascia
Sub pectoral: Above chest wall & below the pectoralis major muscle

PLEASE RETURN FORM VIA ONE OF THE FOLLOWING MECHANISMS:

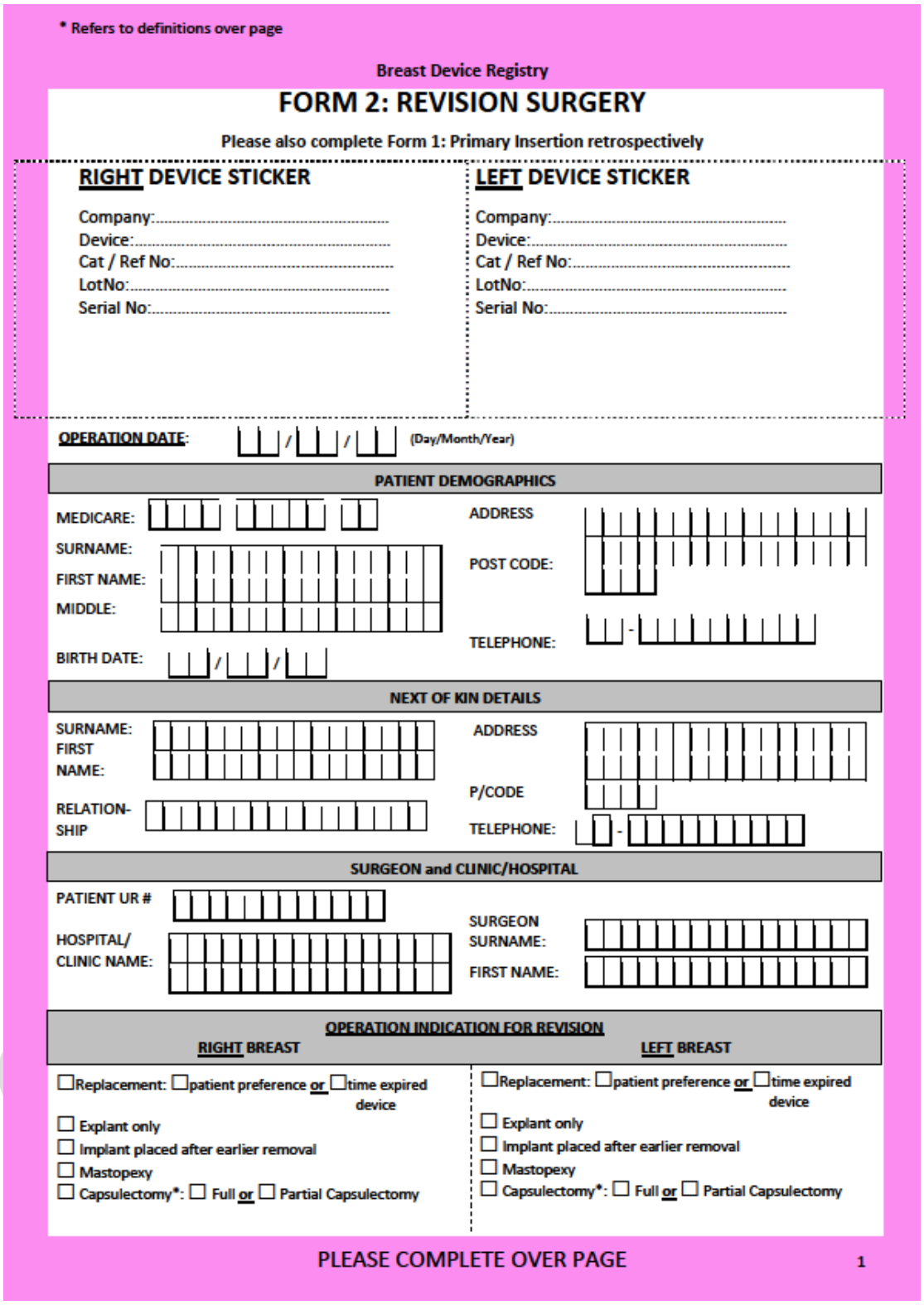
1. BDR box located in reception
2. Place in provided registered post envelopes addressed to:
   BDR Co-ordinator, SPHPM, Level 6, The Alfred Centre, 99 Commercial Road, Melbourne VIC 3004
3. Fax to: (03) 9903 0556

Any questions please contact Renee Best, BDR project coordinator on: (03) 9903 0205 or renee.best@monash.edu

Please use this space if you have any comments, feedback for the BDR, or additional information you think may be relevant:

_____
_____
_____
_____

BACK OF BDR DATA FORM FOR PRIMARY INSERTION



* Refers to definitions over page

Breast Device Registry

FORM 2: REVISION SURGERY

Please also complete Form 1: Primary Insertion retrospectively

RIGHT DEVICE STICKER

Company:
Device:
Cat / Ref No:
LotNo:
Serial No:

LEFT DEVICE STICKER

Company:
Device:
Cat / Ref No:
LotNo:
Serial No:

OPERATION DATE: / / (Day/Month/Year)

PATIENT DEMOGRAPHICS

MEDICARE:
SURNAME:
FIRST NAME:
MIDDLE:
BIRTH DATE: / /
ADDRESS
POST CODE:
TELEPHONE: -

NEXT OF KIN DETAILS

SURNAME:
FIRST NAME:
RELATION-SHIP
ADDRESS
P/CODE
TELEPHONE: -

SURGEON and CLINIC/HOSPITAL

PATIENT UR #
HOSPITAL/ CLINIC NAME:
SURGEON SURNAME:
FIRST NAME:

OPERATION INDICATION FOR REVISION

RIGHT BREAST

☐ Replacement: ☐ patient preference or ☐ time expired device
☐ Explant only
☐ Implant placed after earlier removal
☐ Mastopexy
☐ Capsulectomy*: ☐ Full or ☐ Partial Capsulectomy

LEFT BREAST

☐ Replacement: ☐ patient preference or ☐ time expired device
☐ Explant only
☐ Implant placed after earlier removal
☐ Mastopexy
☐ Capsulectomy*: ☐ Full or ☐ Partial Capsulectomy

PLEASE COMPLETE OVER PAGE 1

FRONT OF BDR DATA FORM FOR REVISION SURGERY

* Refers to definitions over page

Breast Device Registry

FORM 2: REVISION SURGERY

Please also complete Form 1: Primary Insertion retrospectively

RIGHT DEVICE STICKER

Company:.....
Device:.....
Cat / Ref No:.....
LotNo:.....
Serial No:.....

LEFT DEVICE STICKER

Company:.....
Device:.....
Cat / Ref No:.....
LotNo:.....
Serial No:.....

OPERATION DATE: ☐☐/☐☐/☐☐ (Day/Month/Year)

PATIENT DEMOGRAPHICS

MEDICARE: ☐☐☐☐ ☐☐☐☐☐ ☐

SURNAME:
FIRST NAME:
MIDDLE:

BIRTH DATE: ☐☐/☐☐/☐☐

ADDRESS
POST CODE:

TELEPHONE: ☐☐ - ☐☐☐☐☐☐☐☐

NEXT OF KIN DETAILS

SURNAME:
FIRST NAME:

RELATION-SHIP

ADDRESS
P/CODE

TELEPHONE: ☐☐ - ☐☐☐☐☐☐☐☐

SURGEON and CLINIC/HOSPITAL

PATIENT UR #

HOSPITAL/ CLINIC NAME:

SURGEON SURNAME:
FIRST NAME:

OPERATION INDICATION FOR REVISION

RIGHT BREAST

☐Replacement: ☐patient preference or ☐time expired device
☐ Explant only
☐ Implant placed after earlier removal
☐ Mastopexy
☐ Capsulectomy*: ☐ Full or ☐ Partial Capsulectomy

LEFT BREAST

☐Replacement: ☐patient preference or ☐time expired device
☐ Explant only
☐ Implant placed after earlier removal
☐ Mastopexy
☐ Capsulectomy*: ☐ Full or ☐ Partial Capsulectomy

PLEASE COMPLETE OVER PAGE

BACK OF BDR DATA FORM FOR REVISION SURGERY

Appendix 2.
Surgical Item Numbers

45548P
BREAST PROSTHESIS, removal of, as an independent procedure (Anaes.)
Fee: $271.65 **Benefit:** 75% = $203.75 85% = $230.95

45551P
BREAST PROSTHESIS, removal of, with excision of fibrous capsule (Anaes.) (Assist.)
Fee: $435.45 **Benefit:** 75% = $326.60

45553P
BREAST PROSTHESIS, removal and replacement with another prosthesis, following medical complications (such as rupture,
migration of prosthetic material, or capsule formation). (Anaes.) (Assist.)
(See para T8.102 of explanatory notes to this Category)
Fee: $626.75 **Benefit:** 75% = $470.10 85% = $553.05

45554P
BREAST PROSTHESIS, removal and replacement with another prosthesis, following medical complications (such as rupture,migration of prosthetic material, or capsule formation), where new pocket is formed, including excision of fibrous capsule
(Anaes.) (Assist.)
(See para T8.102 of explanatory notes to this Category)
Fee: $686.40 **Benefit:** 75% = $514.80 85% = $612.70

45555P
SILICONE BREAST PROSTHESIS, removal of and replacement with prosthesis other than silicone gel prosthesis (Anaes.)
(Assist.)
(See para T8.102 of explanatory notes to this Category)
Fee: $626.75 **Benefit:** 75% = $470.10

Radiology Item Numbers

Important note:
The codes proposed for implant MRI need to be different from screening MRI in this appendix which is based on criteria for screening and is not applicable to implants

63464P
MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location where the patient is referred by a specialist or by a consultant physician **NOTE: Benefits are payable on one occasion only in any 12 month period** (Anaes.)
(See para DIQ of explanatory notes to this Category)
Fee: $690.00 **Benefit:** 75% = $517.50 85% = $616.30

63467P
MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location where the patient is referred by a specialist or by a consultant physician (Anaes.)
(See para DIQ of explanatory notes to this Category)
Fee: $690.00 **Benefit:** 75% = $517.50 85% = $616.30

Appendix 3

Table 1: Primary implantation[17]

ACHI **book chapter**		**PRIMARY BREAST IMPLANT INSERTION ONLY**						
		2006/ '07	**2007/ '08**	**% change**	**2008/ '09**	**% change**	**2009/ '10**	**% change**
1753 + 45542−00	Primary implantation (Cosmetic and reconstruction)	8603	9400	9.3	9153	-2.6	9910	8.3

Table 2: All procedures relevant to breast devices[17]

ACHI **book chapter**		**Total Procedures**						
		2006/ '07	**2007/ '08**	**% change**	**2008/ '09**	**% change**	**2009/ '10**	**% change**
1753 + 1758 + 45539-00	Includes: Primary implant; Remove implant; Insert tissue expander; Remove tissue expander; Adjust tissue expander; Capsulectomies	15049	16154	7.3	16197	0.3	17393	7.4

References

[1] Editorial, The Observer, Sunday 8th January 2012. "Cosmetic Surgery: Out of a scandal must come proper regulation".

[2] Hals, T 2012, "The troubled history of PIP's implants man in America", *Reuters*, 10 January, Accessed on-line: http://www.reuters.com/article/2012/01/11/us-implants-idUSTRE8090XI20120111

[3] ISAPS http://www.isaps.org/.

[4] ASPS Annual Report to Minister of Health regarding the BIR. Published 2009, 2010 and 2011.

[5] FDA Update on the Safety of Silicone Gel-Filled Breast Implants. US Food and Drug Administration's Center for Devices and Radiological Health. June 2011. Accessed on-line: http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf

[6] Hölmich LR, Friis S, Fryzek JP, et al. Incidence of silicone breast implant rupture. Arch Surg. 2003 Jul;138(7):801-6.

[7] Goodman CM, Cohen V, Thornby J, et al. The lifespan of silicone gel breast imlants and a comparison of mammography ultrasonography and magnetic resonance imaging in detecting rupture: A meta-analysis. Ann Plast Surg 1998; 41(6): 577-85.

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[9] Middleton MS, McNamara MP Jn. Breast Implant Imaging. Lippincott Williams & Wilkins, Philadelphia, 2003.

[10] Dr. M. Reintals; Radiologist specialising in breast and implant MRI imaging (South Australia).

[11] Laurance, J 2012, 'Implant danger extends to all medical devices', *The Independent*, 18 January, Accessed on-line: http://www.independenthealthcare.org.uk/.

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[15] Editorial, The Observer, Sunday 8th January 2012. "Cosmetic Surgery: Out of a scandal must come proper regulation".

[16] Radiological Review. 18 Jan 2012. Dr M Reintals; Radiologist specialising in breast and implant MRI imaging (South Australia).

[17] Australian Institute of Health and Welfare Hospital Statistics: Data Cubes http://www.aihw.gov.au/hospitals-data-cube/?id=10737419462

Breast Device Registry

An International Perspective

This report was prepared as a joint venture by Monash University and the Australasian Foundation for Plastic Surgery.

Presented by: Associate Professor Rodney Cooter, President Australian Society of Plastic Surgeons

Global Summit

Munich May 2012

Acknowledgment

The BDR is a joint development between the Australasian Foundation for Plastic Surgery (AFPS) and the Department of Epidemiology and Preventive Medicine, Monash University (DEPM).

AFPS

The Australasian Foundation for Plastic Surgery (AFPS) is a not for profit scientific institution and is uniquely placed to have an impact on the practice of plastic surgery in the Asia/Pacific region. Its purpose is to improve the safety and quality of health outcomes through education, training, research and communications. Its core values are: integrity, excellence and safety.

AFPS team:

- Dr Richard Barnett, Chairman, Board of Governors (MBBS, FRACS)
- Associate Professor Rodney Cooter, Australian Director, (MBBS MD (Adel) FRACS)
- Dr Howard Klein, New Zealand Director, (M.D.FRACS, FRCSC, FACS)

DEPM Monash University

Monash University has a world-renowned reputation as being an energetic and dynamic university committed to quality education, outstanding research and international engagement. The DEPM, housed in Monash University has been a leader in the development and maintenance of clinical registries and in developing registry science at a national level. It houses several of Australia's largest clinical quality registries.

The DEPM currently houses more than 16 clinical registries. It is well supported by broad expertise and involvement in clinical medicine, whilst at the same time being independent of the major clinical providers.

Monash team:

- Professor John McNeil, Professor and Head of School of Public Health & Preventative Medicine, (MBBS, MSc, PhD, FRACP, FAFPHM)
- Dr Sue Evans, Senior Research Fellow / Associate Director, Centre for Excellence in Patient Safety (RN Grad Dip ClinEpiPhD)
- Ms Renee Best, Project Coordinator Breast Device Registry (BSc(Hons))

Index

The Breast Device Registry

This document provides background to the current status of the newly developed Breast Device Registry (BDR) in Australia. The BDR is a device registry set up to monitor and reduce the probability of adverse outcomes and complications associated with breast implants and breast tissue expanders.

The following section provides information on the need for systematic and complete monitoring of these high risk implantable devices. Furthermore the document outlines methodology specific to the BDR and important periphery factors impacting on registry success, including ratified and robust policies outlining governance structure and process of escalation in the case an outlier is identified.

1. WHY ESTABLISH A BREAST DEVICE REGISTRY

The safety of breast implants, in particular silicone gel filled implants, has been cause for debate since their introduction in 1962. In the past, breast implants were linked to a number of chronic diseases which led to their withdrawal from sale and a number of high profile lawsuits.

In 1991 silicone-gel filled implants were reported to be associated with connective tissue disease. A lack of post-marketing safety data led the US Food and Drug Administration (FDA) to place a voluntary moratorium on the use of silicone gel-filled implants in January 1992.A number of high profile law suits followed, including $3.2 billion awarded to thousands of implant recipients, paid by US manufacturer Dow Corning. This settlement led to the demise of Dow Corning as a breast implant manufacturer.[1] Some lawsuits lasted a number of years, during which a series of epidemiological studies were being conducted. By 2006 the studies demonstrated that implants were not a likely cause of these conditions resulting in the reintroduction to the market of silicone gel implants.

Four years following their reintroduction, two significant adverse events have surfaced:

- *April 2010 a product recall was placed on a French implant brand, PIP*. The recall was initiated due to a reported higher than average rupture rate. Further investigation led to the discovery that PIP implants have been manufactured using industrial grade silicone. Health implications for recipients are yet to be determined. Total sales in Australia is estimated to be approximately 12,500 PIP implants.[2]
- *January 2011 the FDA and TGA reported women with implants have a very low but increased risk of developing Anaplastic Large Cell Lymphoma (ALCL)*.[3-7]Albeit a small risk, there is compelling evidence associating the breast implant with more than 60 reported cases of ALCL. The FDA and American Society of Plastic Surgeons instigated the development of a breast implant registry primarily in response to this discovery.

Without systematically collected data such as that provided by a registry, regulators are unable to provide definitive conclusions to reporting of adverse events. To date, conclusions are drawn from anecdotal data, spontaneous monitoring programs, and self-reporting of adverse events.

2. THE BREAST IMPLANT REGISTRY: A PRECURSOR TO THE BDR

The Australian Society of Plastic Surgeons (ASPS) has been operating a Breast Implant Registry which was established in 1998. The BIR is a Privilege-awarded quality assurance activity and is an opt-in registry. A number of identifying factors led to ASPS seeking guidance from registry scientists to enhance the BIR. In 2011 a collaboration between Australasian Foundation for Plastic Surgery (AFPS) (a subsidiary of ASPS) and Monash University was established to design the newly developed BDR (distinct from the BIR because the BDR will include breast tissue expansion devices as well as implant devices). As the enhancement led to significant changes to the methodology of the registry it was agreed for the BIR will be managed as a separate entity.

The BIR's limitations are believed to be a result of its "opt-in" basis and inability to validate data against the total number of implants sold. Furthermore the BIR relies on the patient paying $25AUDper implant to the implant distributor. In 2010, as a result of the PIP saga, manufacturer's data were released.

These data provided the first true understanding of the BIR capture rate. Data were extrapolated to estimate a 3.4% capture rate of all implants in Australia.

Table 1 outlines factors identified by ASPS supporting the need to transform the BIR into a new registry, the Breast Device Registry.

Table 1: Identifiers of registry success

Failed Breast Implant Registry (BIR)	Ideal Registry (BDR)
Opt in consent (< 30 % population capture)	Opt out consent (near complete recruitment)
Cost to patient	No Cost to patient
Complex data set	Simple but uniform minimum data set
No validation	Validated population based data
Inefficient information transfer	Efficient data collection, storage and retrieval
Privacy concerns	Compliant with Australian National security standards (ISO 20071/2)
Inactive clinical involvement	Proactive multidisciplinary steering committee

3. THE BDR METHODOLOGY

The BDR will collect breast implant and tissue expander performance data, relating to the patient, surgeon, procedure, and device, in order to:

- monitor medium/longer term outcomes including complications;
- provide early detection of faults or quality of care issues; and
- understand patterns of care including revision and removal rates.

Site and Patient recruitment

The BDR aims to be a bi-national registry thereby including Australians and New Zealanders. The BDR will penetrate the breast device population by recruiting surgical sites performing augmentations and revisions (hospitals and private cosmetic surgery clinics). Expansion of the registry will occur on a 'whole-site' by 'whole-site' basis. The team will encourage complete collection by all surgeons working within that site to ensure the registry provides data on complete populations and therefore epidemiologically sound data. Receipt of ethical or the equivalent Medical Advisory Committee approval is a prerequisite for the BDR to instigate data collection at that site.

All patients receiving a breast implant or breast tissue expander at a collaborating site will be included in the registry. Data will be collected for any person undergoing surgery for one or more of the following:

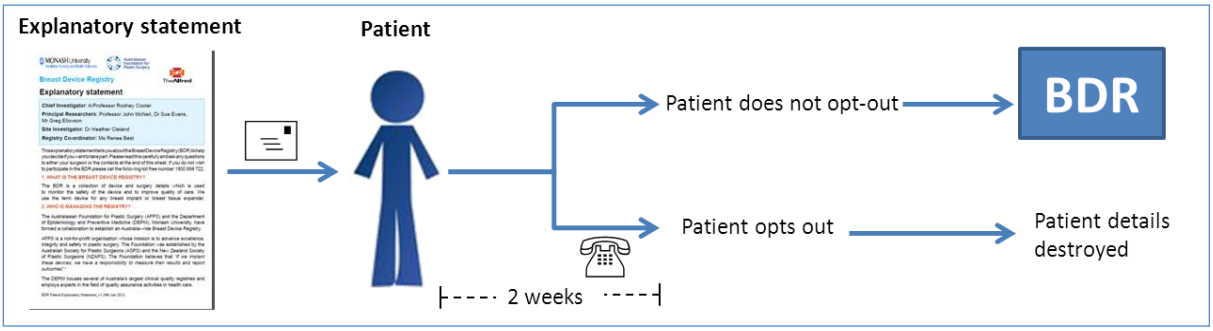
- insertion of breast implant or breast tissue expander;
- explant of breast implant or breast tissue expander; and
- revision surgery, including capsulectomy.

Participation in the registry offers benefit to the patient. Additional to monitoring the safety of the implanted device, the registry provides the patient long term access to their data. A patient can apply to the BDR to retrieve information such as device specifications and date of operation. In Australia medical records are required to be stored by the health care provider for only seven years and therefore it is very feasible for the record to be inaccessible at the time of revision surgery.

A key element to large population capture is to recruit patients via an "opt-out" method. [8]This involves providing a patient an explanatory statement that outlines all the details relevant to their data and the

purposes of the registry. The information provides a toll-free number to call if they choose to "opt-out". Figure 1 depicts the BDR consent process.

Figure 1: Opt out patient consent



Follow-up data

To understand the medium to long-term outcomes that do not present as a revision surgery, the BDR will contact the participant at three time-points following surgery. To date, the methodology and follow-up survey have not been finalised. However patient privacy is paramount and the BDR will establish the optimal communication tool to ensure patient privacy is protected. The time points are suggested to take place at one; five; and ten years following surgery.

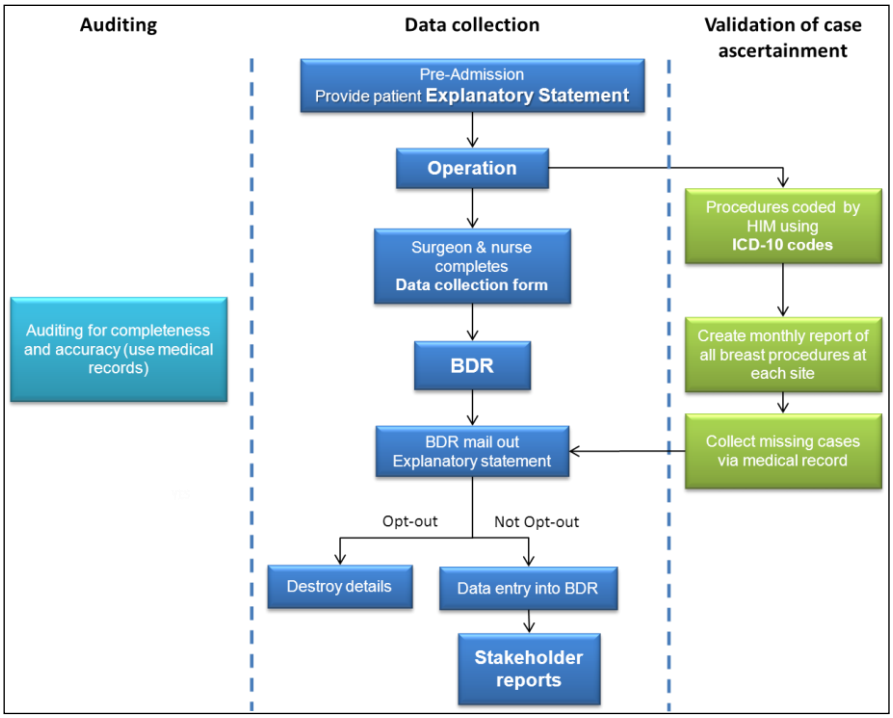
Data collection

Data collection will be carried out by the surgeon with the assistance of an identified theatre staff member. It is proposed a nominated staff member will retrieve the two page (front and back) data collection form (see Appendix B) and complete the front page. Following this, at completion of surgery, the surgeon will complete the back of the form. Once complete, the theatre staff will send data collection forms to the BDR.

Case ascertainment

To ensure the BDR captures whole populations, data collection at each site will be cross referenced with a monthly or quarterly procedural data report. Where a case has been missed, if consent is gained, the information can be retrieved retrospectively from the medical record. A summary of the methodology is outlined in Figure 2.

Figure 2: BDR methodology



4. BDR GOVERNANCE ARRANGEMENTS

The BDR will follow the "Operating Principles and Technical Standards for Australian Clinical Quality Registries" which was endorsed by the Australian Commission on Safety and Quality in Healthcare (ACSQH).[9] Following these guidelines the BDR governance arrangements will include the following arrangements:

- **Steering Committee**: Responsible for the registry and for promoting its activities. An independent chair will be ratified by the multidisciplinary steering group. The membership will include representation from each key stakeholder body. All representatives will be requested to sign a confidentiality agreement to ensure sensitive information brought to this committee is kept secure. This committee is likely to meet biannually. The BDR will endeavour to find a representative without bias from the following stakeholder bodies:
  - device manufacturers;
  - surgeons;
  - consumers; and
  - hospitals, day surgery centres, and clinics.
- **Management committee**: Responsible for the management of the day to day aspects of the registry. This committee will meet regularly and its membership will include registry professionals and statisticians. The key aim is to ensure data accuracy and to feed high priority information into the Steering Committee.
- **Independent complaints system**: A local ethics committee, at which the BDR is an approved study, is deemed an appropriate independent complaints committee. The BDR provides contact details for ethics committees at the bottom of the patient explanatory statement and other relevant documentation.

5. OUTCOMES DATA AND REPORTING

Outcome measures are tools to assess quality of medical care. The outcome measures outlined in this section are a BDR *work in progress*. Once sufficient data is collected, the BDR will generate reports on identified outcome measures. Table 2 outlines proposed outcome measures (formalised outcome measures will be

determined by the steering committee). For example, the rate of revision surgery could be calculated for each site, site type, surgeon, device brand, device specification, and surgical technique.

Each outcome measure will be reported against a number of population groups, proposed groups include:

- All in registry;
- No previous radiotherapy / previous radiotherapy;
- Reconstruction (post cancer and benign) / cosmetic / congenital deformity; and
- Revisions that have linked primary surgery data in BDR.

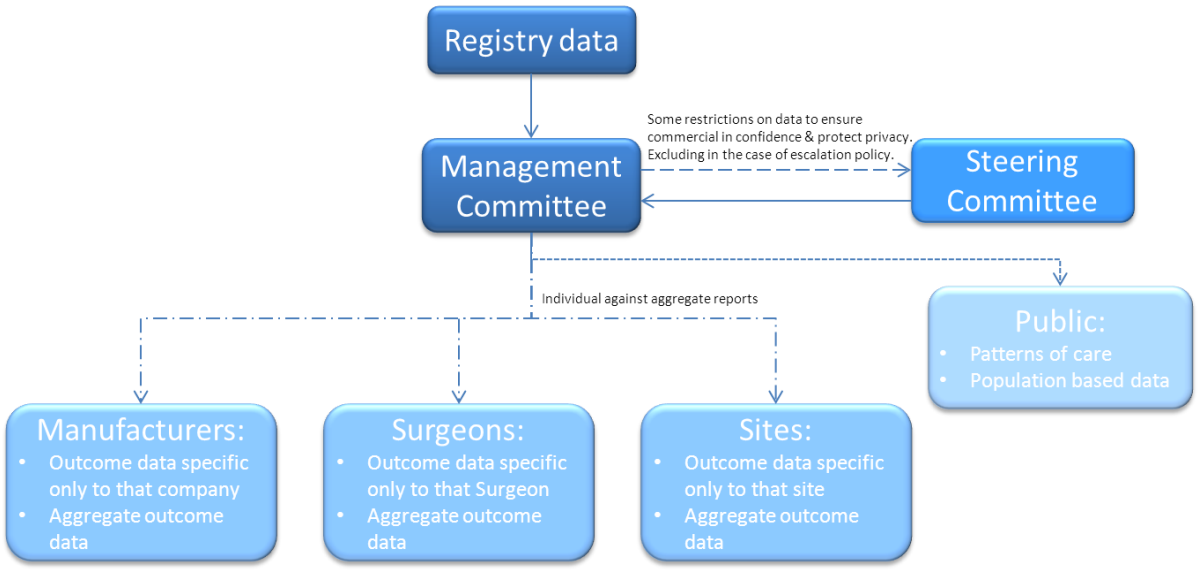
Table 2: Outcome reports for implants and tissue expanders

Outcome measure		Site	Site type	Surgeon	Device Brand	Device Specifications	Surgical technique
		Individual site	Comparative data for: • Public hospital • Private hospital; • Accredited day clinic	Individual surgeon	9 x manufacturers	Any stand out trends in any of: • shell; • fill • shape	Any stand out trends in any of: • Incision; • Plane; • Antibiotic use
Revision surgery	All	✓	✓	✓	✓	✓	✓
	Infection	✓	✓	✓	✓	✓	✓
	Capsular Contracture			✓	✓	✓	✓
Mortality		✓	✓	✓	✓	✓	✓
Patient satisfaction		✓	✓	✓	✓	✓	✓

Reporting structure

Each report will be tailored to the company or person receiving it. The Management committee will be responsible for disseminating data with the appropriate restrictions and de-identification. Reporting restrictions are outlined in the figure below.

Figure 3: BDR data reporting structure



6. ESCALATION POLICIES

A formal escalation policy will be endorsed by the multidisciplinary steering committee. An escalation policy is necessary to ensure all parties understand what processes will occur if an 'outlier' is discovered by the registry.

At any time an outlier is identified the data are always checked for errors, validated against hospital/clinic records and patient demographics and casemix will be assessed for any major shifts.

The formally ratified escalation policy will detail each stakeholder and the line of communication for level two and three. The escalation policy is proposed to include three levels:

A **level one** alert is flagged if an outlier has been found to be 2 standard deviations from the mean for two consecutive quarters (3 month periods). This stage would typically involve direct contact with only the stakeholder involved.

A **level two** alert is a response to an outlier that has been identified to be three standard deviations from the mean for two consecutive quarters. The communication line is yet to be determined.

A **level three** alert is flagged if the level two is persisting for more than two consecutive quarters. The communication line at this level is yet to be determined.

7. INTERNATIONAL BENCHMARKING: A PROPOSAL FOR AN INTERNATIONAL SOCIETY

With a number of countries considering establishing a breast implant registry and others with registries in their infancy it will soon be necessary to bring together an international collaboration. The collaboration is required to unify data collection and statistical analysis, in order to enable international comparison and benchmarking.

It is anticipated breast registries will interpret learnings and protocols already established in currently operational registry collaborations such as the International Society of Arthroplasty Registries (ISAR). ISAR is a collaboration of 23 registries spanning more than 13 countries which has established aims, objectives and policies. Overall the ISAR aims to provide a support network for registries; encourage sharing of information; and encourage collaborative activities.

With interpretation of ISAR's activities and preliminary thoughts of the BDR it is proposed to establish an International Collaboration of Breast Registry Activities (ICOBRA). Such a collaboration will establish aims, objectives, and core requirements of membership to encourage systemisation and streamlining of the breast registries.

A mission statement will draw the collaboration together to have a focus on improving outcomes of individuals undergoing implant surgery.

Aims of ICOBRA would incorporate:

- Providing a support network for all breast registries; and
- Enhance information sharing and collaborations.

Outlined in its objectives ICOBRA would seek to establish:

- conformity of terminology, including validating definitions; and
- standardisation of statistical analysis, this is to help reduce confusion when comparing results of registries

This international collaboration will work together to enable international comparison of data. To do so each contributing registry would need to adhere to agreed protocols outlining the following:

- a pre-determined core minimum data set ensuring it includes all data fields desired for benchmarking (eg. outcome data such as rate of complications)
- data definitions to be agreed upon and identical at both data collection and data entry; and
- data to be collected following a population based methodology with a near complete population capture.

8. DETERMINING DEVICE EXPIRY

To date there is no agreed timeframe at which an implant in-situ should be explanted (device expiry). Most breast implants will eventually rupture. Information to date suggests in general terms implants will last about 10 – 15 years with a low rupture rate of 1%-1.3% per year.[10] Between 11 and 20 years most will rupture and

after 20 years few will still be intact.[11] Significantly high rupture rates of these devices has been known for many years with 20% ten year rupture rate and 50% 15 year rupture rates reported in 1998.[12]

Many clinicians recommend replacement at 10 - 15 years post-implantation when taking into consideration the above data regarding rupture rates. However there is a huge void of evidence and this is one of many areas where registries' data can be used to inform current clinical practice.

Appendices:

- Appendix A: Patient Explanatory statement
- Appendix B: Data collection tools:
  - Form 1: Primary insertion
  - Form 2: Revision surgery
  - Definitions page

Appendix A: Patient explanatory statement

The BDR explanatory statement will be printed in a booklet format. The words within the booklet are below.

Explanatory statement

Chief Investigator: A/Professor Rodney Cooter
Principal Researchers: Professor John McNeil; Dr Sue Evans; Mr Greg Eliovson.
Site Investigator: Dr Heather Cleland
Registry Co-ordinator: Ms Renee Best

This explanatory statement tells you about the Breast Device Registry (BDR) to help you decide if you want to take part. Please read this carefully and ask any questions to either your surgeon or the contacts at the end of this sheet. If you do not wish to participate in the BDR please call 1800 998 722.

1. WHAT IS THE BREAST DEVICE REGISTRY?

The BDR is a collection of device and surgery details which is used to monitor the safety of the device and to improve quality of care. We use the term device for any breast implant or breast tissue expander.

The BDR has been approved by the Human Research Ethics Committee at the Alfred Hospital.

2. WHO IS MANAGING THE REGISTRY?

The Australasian Foundation for Plastic Surgery (AFPS) and the Department of Epidemiology and Preventive Medicine (DEPM), Monash University, have formed a collaboration to establish an Australian-wide Breast Device Registry.

AFPS is a not-for-profit organisation whose mission is to advance excellence, integrity and safety in plastic surgery. The Foundation was established by the Australian Society for Plastic Surgeons (ASPS) and the New Zealand Society of Plastic Surgeons (NZAPS).

The Foundation believes that “if we implant these devices, we have a responsibility to measure their results and report outcomes” and “…that information should be recorded and made available to the patient”.

The DEPM houses several of Australia’s largest clinical quality registries and employs experts in the field of quality assurance activities in health care.

3. WHAT IS THE PURPOSE OF THE BDR?

The BDR will be used to monitor the safety of breast devices and their impact on the health and wellbeing of recipients. Collecting surgical details will help us identify optimal surgical techniques and provide quality of care feedback to surgeons and manufacturers.

Importantly, the BDR is also a communication line between the AFPS and device recipients, enabling direct notification of device re-calls or device-related complications. The BDR is an information ‘safe-keep’ of your implant details which is of importance in the event of future complications.

4. WHAT DOES PARTICIPATION IN THIS PROJECT INVOLVE?

The following information will be collected from your medical record and sent to the BDR:

- Name, date of birth;
- Address and contact details (required for follow up questionnaire and in the case of device recall);
- The name and telephone number of the contact person you recorded on the admission form you completed when admitted to hospital for the implant surgery (only required if we are unable to contact you. If this is the case the reason for telephoning will not be disclosed to this person);
- Implant details (serial number, type, etc);
- Surgeon details;
- Operation notes (eg plane of implantation); and
- If applicable: revision details (implant removal or replacement).

You will be contacted by the BDR staff, at three time points:

- 1 year post surgery; (telephone or email);
- 5 years post surgery (by means specified on first contact); and
- 10 years post-surgery.

At each stage the BDR will ask you to complete a short survey to understand how satisfied you are with your surgery and if not, why.

Appendix A: Patient explanatory statement

5. WHAT ARE THE BENEFITS TO PARTICIPATION?

The BDR will provide you with your surgery details, at any time, for any reason. Your surgery details are important to provide to your next doctor if you experience complications or require a revision. Your doctor may not have access to this information as medical records are only required to be stored for seven years after last visit.

The registry also provides a direct line of communication between yourself and the BDR. This is important in case your device is found to be unsafe and requires a re-call. A recall of an implant brand has happened in the past and the registry was able to contact the recipients who had received that implant brand. Also you can contact the BDR to report any complications you may experience.

Data in the BDR only becomes meaningful when details of all implanted devices are recorded (or near enough). Your participation in this registry will contribute to ensuring the overall health and wellbeing of people undergoing breast device surgery in the future.

6. WHAT ARE THE POSSIBLE RISKS?

Researchers directly involved in the collection of data will have access to your medical record. To ensure that your private information is safeguarded, registry staff must comply with very strict privacy principles. Researchers will not release your identifiable information to any person or organisation outside the registry. When data is used for analysis your record will be assigned a de-identified code. No identifiable information will be reported.

7. DO I HAVE TO TAKE PART IN THE BDR?

You do not have to take part in the BDR; participation is voluntary. If you decide to take part and later change your mind, you are free to withdraw and any details that may have been collected will be deleted. As this registry is to improve quality of care it is an opt-off registry. This means that your details will automatically be included in the registry unless you let us know that you don't want to participate. Your involvement in the BDR will not change or have any impact on, your relationship with your doctor or service.

If you do not contact us within 2 weeks on the free call number 1800 998 722 will we assume that you are happy for us to collect this information.

8. WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

Data within the registry must be identifiable in order for the BDR to contact you in the case of device re-call; to provide you with information at your request; and to contact you for the follow up survey. It will be safeguarded through State and Commonwealth privacy laws. Information will be stored securely with access restricted only to registry officers.

Any research or release of outcomes will use unidentifiable information. Research using this registry data will require researchers to have it approved by an ethics committee. By taking part in the registry you will be agreeing to have this information used for research which aims to investigate quality of care issues relating to breast device surgery.

As this is an ongoing registry, data will be kept indefinitely in a secure environment.

9. CAN I ACCESS INFORMATION KEPT ABOUT ME?

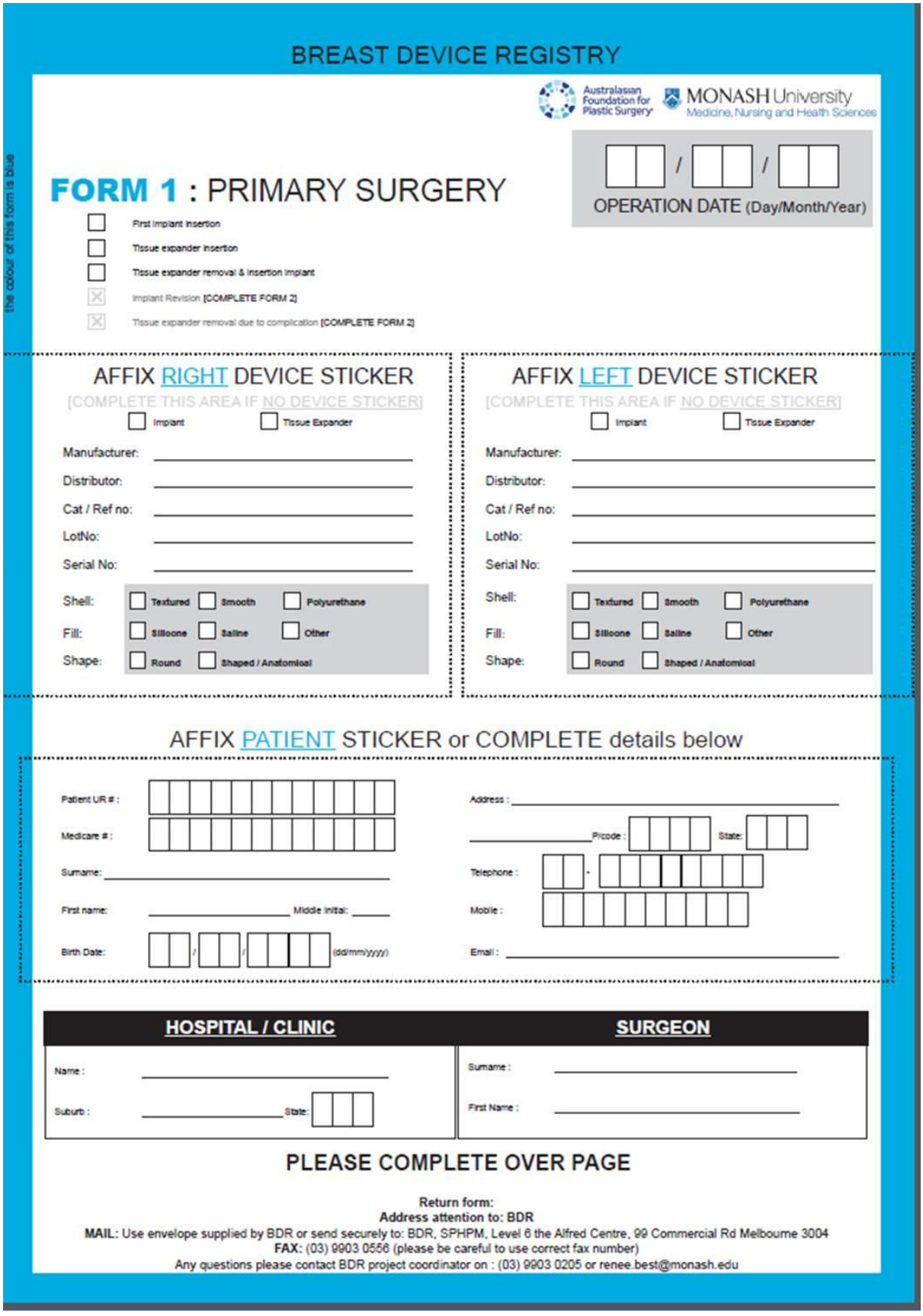
Yes. Your access to this information can be valuable to you in the unlikely event of a complication. Forms to apply for access to your information and to notify the registry of change of address/phone are available by contacting the BDR.

10. WHO CAN I CONTACT?

To opt-out please call the free call number 1800 998 722. To request an information retrieval form, report any complications, or for general information, please call the BDR Co-ordinator: (03) 9903 0205 or email renee.best@monash.edu.

This study has been approved by the Ethics Committee at Alfred Health. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study, or your rights as a participant, you may also contact KordulaDunscombe of the AHREC, telephone (03) 9508 1375.

Appendix B: Data collection forms



BREAST DEVICE REGISTRY

Australasian Foundation for Plastic Surgery · MONASH University Medicine, Nursing and Health Sciences

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FORM 1 : PRIMARY SURGERY

OPERATION DATE (Day/Month/Year)

- ☐ First implant insertion
- ☐ Tissue expander insertion
- ☐ Tissue expander removal & insertion implant
- ☒ Implant Revision [COMPLETE FORM 2]
- ☒ Tissue expander removal due to complication [COMPLETE FORM 2]

AFFIX RIGHT DEVICE STICKER

[COMPLETE THIS AREA IF NO DEVICE STICKER]

☐ Implant ☐ Tissue Expander

Manufacturer: _____

Distributor: _____

Cat / Ref no: _____

LotNo: _____

Serial No: _____

Shell: ☐ Textured ☐ Smooth ☐ Polyurethane

Fill: ☐ Silicone ☐ Saline ☐ Other

Shape: ☐ Round ☐ Shaped / Anatomical

AFFIX LEFT DEVICE STICKER

[COMPLETE THIS AREA IF NO DEVICE STICKER]

☐ Implant ☐ Tissue Expander

Manufacturer: _____

Distributor: _____

Cat / Ref no: _____

LotNo: _____

Serial No: _____

Shell: ☐ Textured ☐ Smooth ☐ Polyurethane

Fill: ☐ Silicone ☐ Saline ☐ Other

Shape: ☐ Round ☐ Shaped / Anatomical

AFFIX PATIENT STICKER or COMPLETE details below

Patient UR # :

Medicare # :

Surname: _____

First name: _____ Middle initial: _____

Birth Date: / / (dd/mm/yyyy)

Address : _____

_____ Pcode : State:

Telephone : -

Mobile :

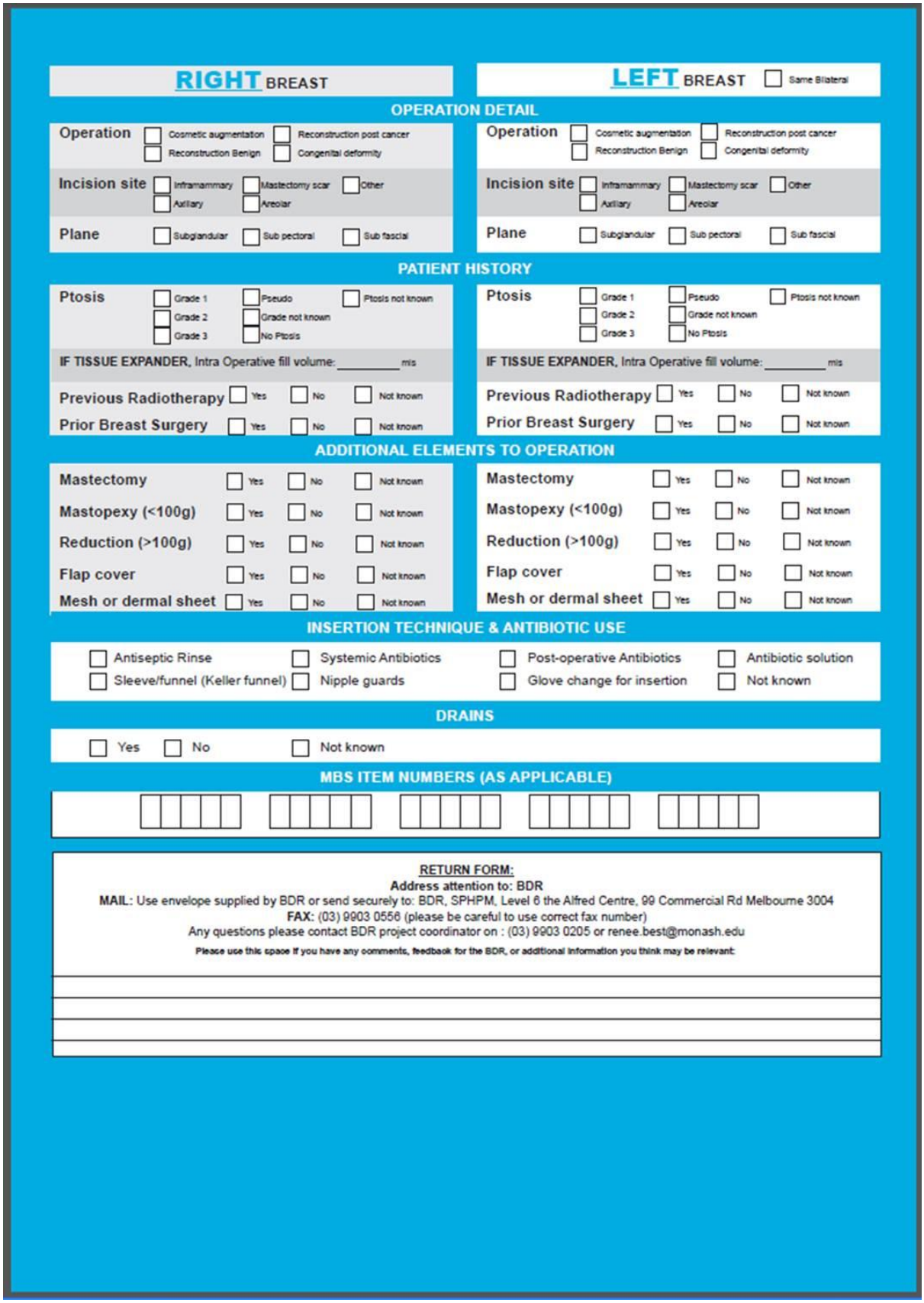
Email : _____

HOSPITAL / CLINIC	SURGEON
Name : _____	Surname : _____
Suburb : _____ State:	First Name : _____

PLEASE COMPLETE OVER PAGE

Return form:
Address attention to: BDR
MAIL: Use envelope supplied by BDR or send securely to: BDR, SPHPM, Level 6 the Alfred Centre, 99 Commercial Rd Melbourne 3004
FAX: (03) 9903 0556 (please be careful to use correct fax number)
Any questions please contact BDR project coordinator on : (03) 9903 0205 or renee.best@monash.edu

Appendix B: Data collection forms



RIGHT BREAST

LEFT BREAST ☐ Same Bilateral

OPERATION DETAIL

	RIGHT BREAST	LEFT BREAST
Operation	☐ Cosmetic augmentation ☐ Reconstruction post cancer ☐ Reconstruction Benign ☐ Congenital deformity	☐ Cosmetic augmentation ☐ Reconstruction post cancer ☐ Reconstruction Benign ☐ Congenital deformity
Incision site	☐ Inframammary ☐ Mastectomy scar ☐ Other ☐ Axillary ☐ Areolar	☐ Inframammary ☐ Mastectomy scar ☐ Other ☐ Axillary ☐ Areolar
Plane	☐ Subglandular ☐ Sub pectoral ☐ Sub fascial	☐ Subglandular ☐ Sub pectoral ☐ Sub fascial

PATIENT HISTORY

	RIGHT BREAST	LEFT BREAST
Ptosis	☐ Grade 1 ☐ Pseudo ☐ Ptosis not known ☐ Grade 2 ☐ Grade not known ☐ Grade 3 ☐ No Ptosis	☐ Grade 1 ☐ Pseudo ☐ Ptosis not known ☐ Grade 2 ☐ Grade not known ☐ Grade 3 ☐ No Ptosis
IF TISSUE EXPANDER, Intra Operative fill volume:	_____ mls	_____ mls
Previous Radiotherapy	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Prior Breast Surgery	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known

ADDITIONAL ELEMENTS TO OPERATION

	RIGHT BREAST	LEFT BREAST
Mastectomy	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Mastopexy (<100g)	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Reduction (>100g)	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Flap cover	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Mesh or dermal sheet	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known

INSERTION TECHNIQUE & ANTIBIOTIC USE

☐ Antiseptic Rinse ☐ Systemic Antibiotics ☐ Post-operative Antibiotics ☐ Antibiotic solution
☐ Sleeve/funnel (Keller funnel) ☐ Nipple guards ☐ Glove change for insertion ☐ Not known

DRAINS

☐ Yes ☐ No ☐ Not known

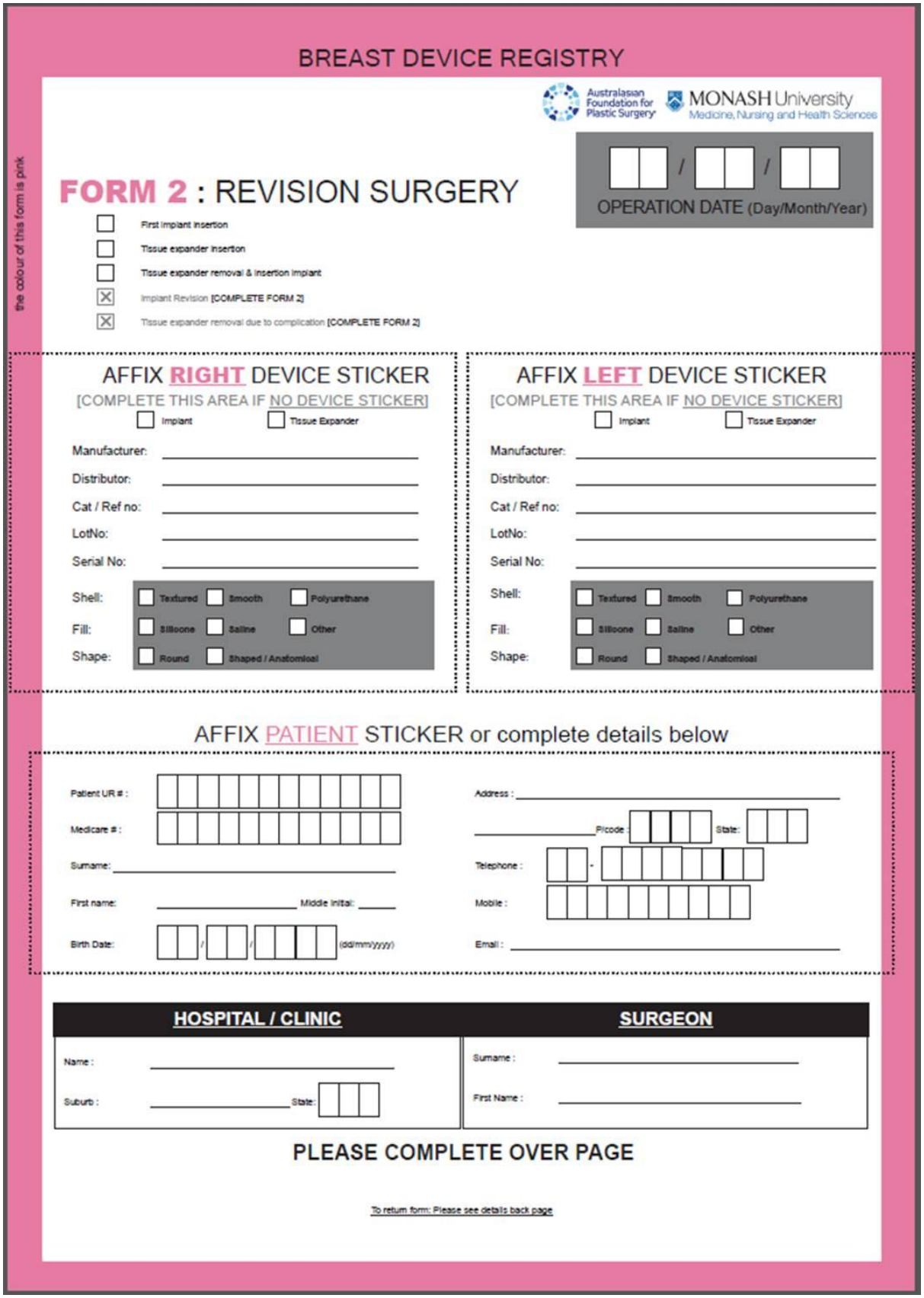
MBS ITEM NUMBERS (AS APPLICABLE)

☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐

RETURN FORM:
Address attention to: BDR
MAIL: Use envelope supplied by BDR or send securely to: BDR, SPHPM, Level 6 the Alfred Centre, 99 Commercial Rd Melbourne 3004
FAX: (03) 9903 0556 (please be careful to use correct fax number)
Any questions please contact BDR project coordinator on : (03) 9903 0205 or renee.best@monash.edu

Please use this space if you have any comments, feedback for the BDR, or additional information you think may be relevant:

Appendix B: Data collection forms



BREAST DEVICE REGISTRY

Australasian Foundation for Plastic Surgery | MONASH University Medicine, Nursing and Health Sciences

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FORM 2 : REVISION SURGERY

OPERATION DATE (Day/Month/Year)

- ☐ First implant insertion
- ☐ Tissue expander insertion
- ☐ Tissue expander removal & insertion implant
- ☒ Implant Revision [COMPLETE FORM 2]
- ☒ Tissue expander removal due to complication [COMPLETE FORM 2]

AFFIX RIGHT DEVICE STICKER

[COMPLETE THIS AREA IF NO DEVICE STICKER]

☐ Implant ☐ Tissue Expander

Manufacturer:
Distributor:
Cat / Ref no:
LotNo:
Serial No:
Shell: ☐ Textured ☐ Smooth ☐ Polyurethane
Fill: ☐ Silicone ☐ Saline ☐ Other
Shape: ☐ Round ☐ Shaped / Anatomical

AFFIX LEFT DEVICE STICKER

[COMPLETE THIS AREA IF NO DEVICE STICKER]

☐ Implant ☐ Tissue Expander

Manufacturer:
Distributor:
Cat / Ref no:
LotNo:
Serial No:
Shell: ☐ Textured ☐ Smooth ☐ Polyurethane
Fill: ☐ Silicone ☐ Saline ☐ Other
Shape: ☐ Round ☐ Shaped / Anatomical

AFFIX PATIENT STICKER or complete details below

Patient UR # :
Medicare # :
Surname:
First name: Middle initial:
Birth Date: / / (dd/mm/yyyy)

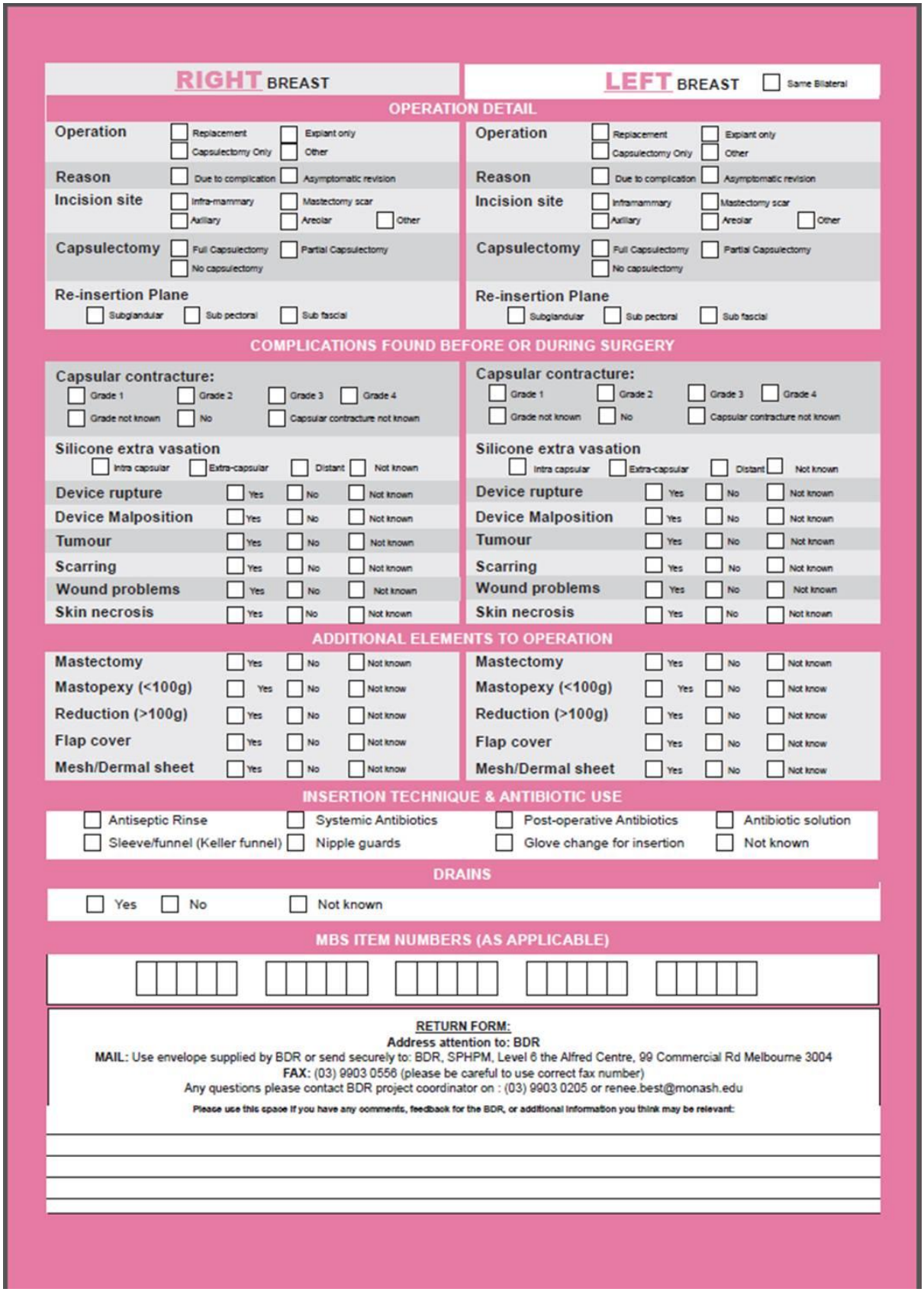
Address :
P/code : State:
Telephone : -
Mobile :
Email :

HOSPITAL / CLINIC	SURGEON
Name :	Surname :
Suburb : State:	First Name :

PLEASE COMPLETE OVER PAGE

To return form: Please see details back page

Appendix B: Data collection forms



RIGHT BREAST | **LEFT BREAST** ☐ Same Bilateral

OPERATION DETAIL

	RIGHT BREAST	LEFT BREAST
Operation	☐ Replacement ☐ Explant only ☐ Capsulectomy Only ☐ Other	☐ Replacement ☐ Explant only ☐ Capsulectomy Only ☐ Other
Reason	☐ Due to complication ☐ Asymptomatic revision	☐ Due to complication ☐ Asymptomatic revision
Incision site	☐ Infra-mammary ☐ Mastectomy scar ☐ Axillary ☐ Areolar ☐ Other	☐ Inframammary ☐ Mastectomy scar ☐ Axillary ☐ Areolar ☐ Other
Capsulectomy	☐ Full Capsulectomy ☐ Partial Capsulectomy ☐ No capsulectomy	☐ Full Capsulectomy ☐ Partial Capsulectomy ☐ No capsulectomy
Re-insertion Plane	☐ Subglandular ☐ Sub pectoral ☐ Sub fascial	☐ Subglandular ☐ Sub pectoral ☐ Sub fascial

COMPLICATIONS FOUND BEFORE OR DURING SURGERY

	RIGHT BREAST	LEFT BREAST
Capsular contracture:	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade not known ☐ No ☐ Capsular contracture not known	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade not known ☐ No ☐ Capsular contracture not known
Silicone extra vasation	☐ Intra capsular ☐ Extra-capsular ☐ Distant ☐ Not known	☐ Intra capsular ☐ Extra-capsular ☐ Distant ☐ Not known
Device rupture	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Device Malposition	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Tumour	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Scarring	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Wound problems	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Skin necrosis	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known

ADDITIONAL ELEMENTS TO OPERATION

	RIGHT BREAST	LEFT BREAST
Mastectomy	☐ Yes ☐ No ☐ Not known	☐ Yes ☐ No ☐ Not known
Mastopexy (<100g)	☐ Yes ☐ No ☐ Not know	☐ Yes ☐ No ☐ Not know
Reduction (>100g)	☐ Yes ☐ No ☐ Not know	☐ Yes ☐ No ☐ Not know
Flap cover	☐ Yes ☐ No ☐ Not know	☐ Yes ☐ No ☐ Not know
Mesh/Dermal sheet	☐ Yes ☐ No ☐ Not know	☐ Yes ☐ No ☐ Not know

INSERTION TECHNIQUE & ANTIBIOTIC USE

☐ Antiseptic Rinse ☐ Systemic Antibiotics ☐ Post-operative Antibiotics ☐ Antibiotic solution
☐ Sleeve/funnel (Keller funnel) ☐ Nipple guards ☐ Glove change for insertion ☐ Not known

DRAINS

☐ Yes ☐ No ☐ Not known

MBS ITEM NUMBERS (AS APPLICABLE)

☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐

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Appendix B: Data collection forms

Australasian Foundation for Plastic Surgery | MONASH University Medicine, Nursing and Health Sciences

BREAST DEVICE REGISTRY
DEFINITIONS

CAPSULAR CONTRACTURE: BAKER CLASSIFCATION	**Grade I**: breast is soft with no palpable capsule & looks natural **Grade II**: breast is slightly firm, with a palpable capsule & looks natural **Grade III** (moderate): the breast is firm with an easily palpable capsule and looks abnormal **Grade IV** (severe): the breast is hard, cold, painful, and distorted
CAPSULECTOMY:	
FULL	Complete removal of capsule
PARTIAL	Capsule is surgically released and/or partially removed through an incision within the breast area
INCISION SITE:	
AREOLA	Around the lower border of the nipple/areola
AXILLARY	through the armpit
INFRA-MAMMARY	In the fold of under the breast
MASTECTOMY	Via the mastectomy scar
PLANE:	
SUB GLANDULAR	Beneath the gland and above the muscular fascia
SUB FASCIAL	Implant above pectoralis muscle but below the pectoralis fascia
SUB PECTORAL	Above chest wall & below the pectoralis major muscle
PTOSIS GRADE	**Grade 1**: nipple is the level of the breast crease **Grade 2**: nipples have dropped below level of breast crease, but higher than majority of breast **Grade 3**: nipples below breast crease at level of maximum projection **Pseudo**: Nipple is normal level but breast has slid down below level of breast crease giving appearance of bottomed-out breast.
SLEEVE / FUNNEL	A skin barrier protector such as funnel/skin adhesive film over incision

MBS item numbers

45524	MAMMAPLASTY AUGMENTATION, for significant breast asymmetry where the augmentation is limited to 1 breast
45527	MAMMAPLASTY AUGMENTATION, (unilateral), following mastectomy
45528	MAMMAPLASTY, AUGMENTATION, bilateral, not being a service to which Item 45527 applies, where it can be demonstrated that surgery is indicated because of malformation of breast tissue (excluding hypomastia), disease or trauma of the breast (other than trauma resulting from previous elective cosmetic surgery
45552	BREAST PROSTHESIS, removal of, with excision of fibrous capsule and replacement of prosthesis
45553	BREAST PROSTHESIS, removal and replacement with another prosthesis, following medical complications (such as rupture, migration of prosthetic material, or capsule formation)
45554	BREAST PROSTHESIS, removal and replacement with another prosthesis, following medical complications (such as rupture, migration of prosthetic material, or capsule formation), where new pocket is formed, including excision of fibrous capsule
45555	SILICONE BREAST PROSTHESIS, removal of and replacement with prosthesis other than silicone gel prosthesis
45548	BREAST PROSTHESIS, removal of, as an independent procedure
45551	BREAST PROSTHESIS, removal of, with excision of fibrous capsule
45539	BREAST RECONSTRUCTION (unilateral), following mastectomy, using tissue expansion - insertion of tissue expansion unit and all attendances for subsequent expansion injections
45542	BREAST RECONSTRUCTION (unilateral), following mastectomy, using tissue expansion - removal of tissue expansion unit and insertion of permanent prosthesis
45559	TUBEROUS, TUBULAR OR CONSTRICTED BREAST, where it can be demonstrated, correction of by simultaneous mastopexy and augmentation of (unilateral)

References

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2. Jeeves; A.L., Cooter; R.D. Transforming Autralia's Breast Implant Registry. Medical Journal of Australia 2012;196(4):232-4.
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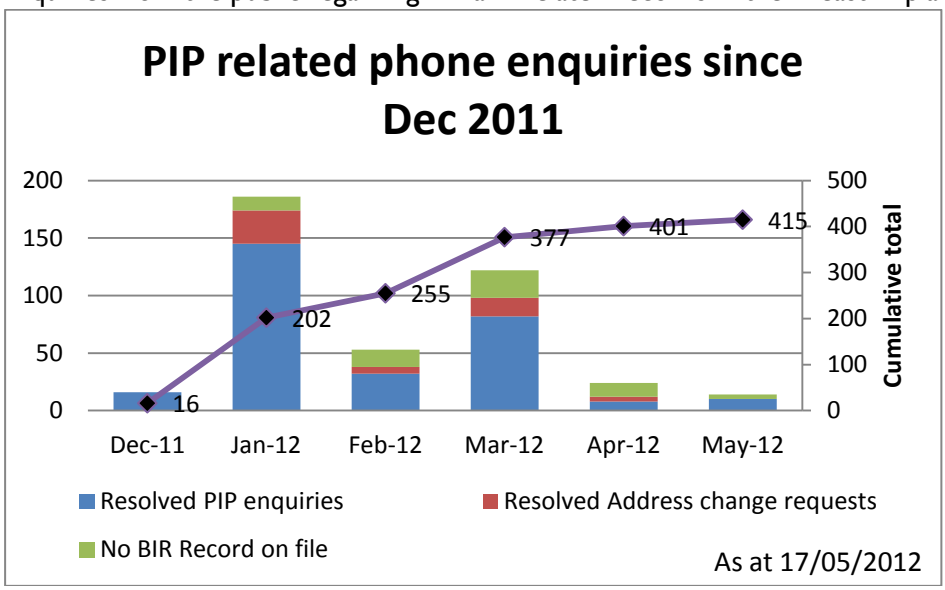
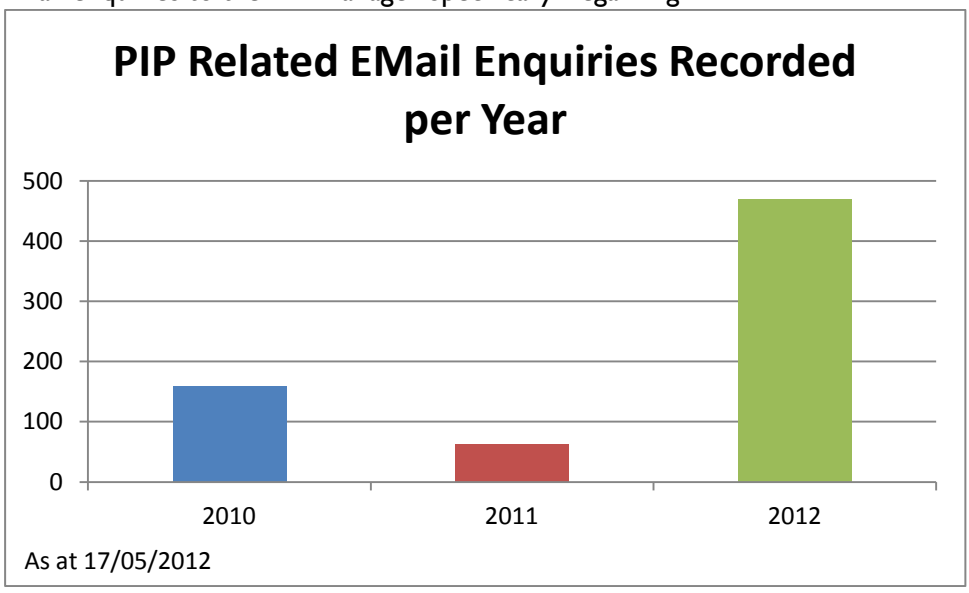
Australian Society *of* Plastic Surgeons

18 May 2012

Enquiries from the public regarding PIP and related records in the Breast Implant Registry



Email enquiries to the BIR Manager Specifically Regarding PIP



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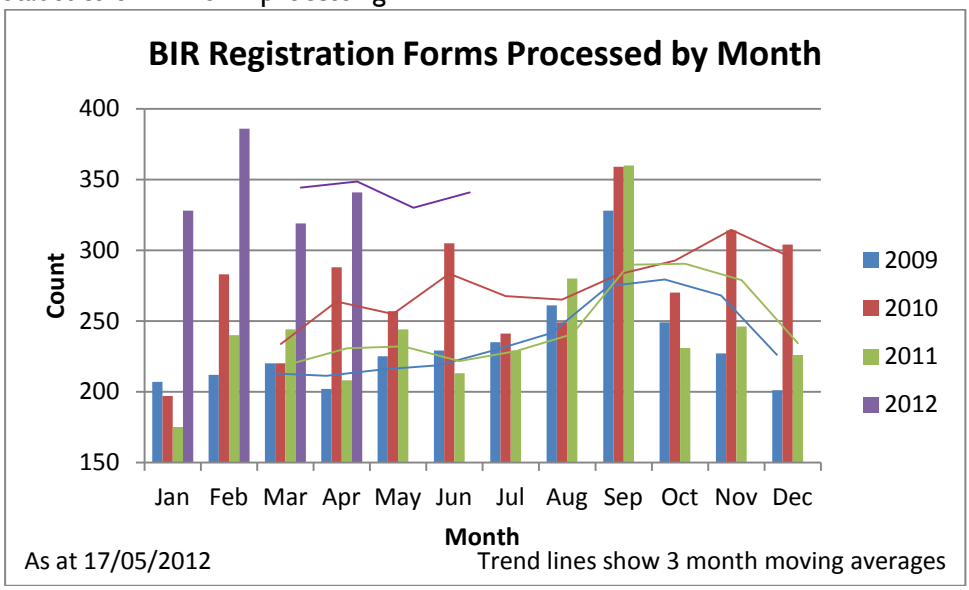
Incorporated in the ACT with members' liability limited

Statistics of BIR form processing



Greg Eliovson

From: Gaye Phillips
Sent: Tuesday, 13 March 2012 2:37 PM
To: Gregory Eliovson
Subject: FW: Attention: Associate Professor Rod Cooter, President Australian Society of Plastic Surgeons - PIP breast implants

Follow Up Flag: Follow up
Flag Status: Completed

Categories: PIP corresp

From: [Removed for confidentiality]
Sent: Tuesday, 13 March 2012 2:33 PM
To: Gaye Phillips
Subject: RE: Attention: Associate Professor Rod Cooter, President Australian Society of Plastic Surgeons - PIP breast implants

13 March 2012

Associate Professor Rod Cooter
President
Australian Society of Plastic Surgeons

Dear Mr Cooter

Thank you for your response of 13 March 2012. I truly appreciate you taking the time to respond.

I would like to clarify one of the statements I made to you in my original email of 2/3 when I stated "***the majority of ASPS plastic surgeons are charging full fees"***. By "**full fees"**, I mean the plastic surgeon is quoting their standard breast implant removal and replacement fee, less any medicare or private health rebates that may apply. And by "**majority'**, I do not mean the majority of all 300 ASPS members, I mean the majority of plastic surgeons who were the original implanting surgeons of PIP breast implants, who are now being approached by patients to remove and replace their PIP breast implants, whether ruptured or not. I would also like to point out that this statement has been made based on verbal reports to me from a small number of Australian women who have PIP breast implants and I am not in possession of any written quotes from ASPS plastic surgeons to confirm the accuracy of their claims. I also acknowledge that a number of ASPS plastic surgeons are removing PIP breast implants free of charge. I apologise that my original statement may not have been clear – I am unfamiliar with writing letters such as these - I hope that I have now been able to clarify my point for you.

I note your comments about there being circumstances in which certain medicare item numbers may be used for the removal of PIP breast implants, regardless of rupture. As you are probably aware, these medicare rebates are usually under $600 yet the total fee charged by the plastic surgeon for removal and replacement of PIP breast implants can exceed $13,000. It appears that some patients with defective PIP breast implants can be faced with out of pocket fees in excess of $12,000 (though is some cases, this can be much lower, depending on the individual plastic surgeon). Whether this out of pocket fee is $5,000 or $12,000, this can be unaffordable for the average Australian woman and some are faced with the burden of knowing they have a ruptured PIP implant but are unable to afford the removal and replacement. I understand that you cannot instruct your members to charge or not charge for the removal of PIP implant and that fees must be a matter of determination by individual medical practitioners. However I am hoping

that this information on the financial difficulty some women are facing, may be passed on to your members and to the TGA so that further rebates may be made considered.

Thank you once again for your letter and for the clarification of information.

Yours sincerely

[Removed for confidentiality]

From: Gaye Phillips [mailto:GPhillips@plasticsurgery.org.au]
Sent: Tuesday, 13 March 2012 11:15 AM
To: [Removed for confidentiality]
Cc: rcooter@plasticsurgery.org.au
Subject: Attention: Associate Professor Rod Cooter, President Australian Society of Plastic Surgeons - PIP breast implants

13 March 2012
This email is sent on behalf of Associate Professor Rod Cooter, President, Australian Society of Plastic Surgeons.

Dear Ms [Removed for confidentiality]
Thank you for taking the time to write to me. I hope your personal health circumstances are improving. This is a worrying time for many Australians. At the outset, let me say that, as President of the Australian Society of Plastic Surgeons, it is regrettable that your email narrates an experience which would seem to have been unsympathetic to your circumstances. I trust you are aware that you have the right to report any complaint of professional misconduct by a medical practitioner to the Medical Board for its investigation and determination.

In my experience, our members are very concerned about the current PIP situation. In fact we wrote to the TGA with our concerns in 2010 and our members continue to report cases to the TGA. Ultimately, the Government is accountable to make decisions on the management of the PIP situation in Australia. Our Society can only make recommendations and offer advice through its representation on the Chief Medical Officer's Advisory Group.

A recent survey of our members showed that, of the more than 12,000 PIP implants used Australia, the vast majority of these were not implanted by our members. Medical practitioners, other than specialist plastic surgeons, were the main users of these particular implants.

You claim that *"the majority of ASPS plastic surgeons are charging full fees"*. I am surprised by your claim. You will be aware that the ACCC prohibits the price fixing of medical fees, in any circumstance, so we are not permitted by law to instruct our members to charge or not charge for the removal of PIP implants. Fees must be a matter of determination by individual medical practitioners. We have distributed all relevant and up to date information about the PIP situation to our members including confirmation, which we proactively sought from the head of Medicare, that there are circumstances in which certain item numbers may be used. That is, where patients present with a PIP implant, whether or not it is ruptured, circumstances could be such that it is reasonable to apply a Medicare Item number. Where this is not the case, I am personally aware of many instances in which our members have removed the PIP implants, free of charge, even though our member was in almost all cases, not the original implanting doctor. There are more than 300 members of our Society and all are fully trained specialist plastic surgeons and accredited as specialist surgeons by the Australian Medical Council. I would be pleased to see your evidence for your claim that, of our membership of 300 surgeons, *"the majority of ASPS plastic surgeons are charging full fees"*.

There is a level of genuine anxiety in the community in relation to the PIP implants. Patient safety is our priority and as specialist plastic surgeons our recommendation is always to err on the side of caution. If anyone has concerns, they should consult with their doctor or surgeon for an individual assessment. We welcome the announcement over the weekend from the Minister for Health and Ageing, the Hon Tanya Plibersek MP, that Medicare will

subsidise MRI scans of PIP implants to assess if they're ruptured as this goes some way to alleviate community anxiety. For more information about receiving a scan, you can view the Department of Health website: http://www.health.gov.au/internet/main/publishing.nsf/Content/medicare-eligible-mri-service-for-pip-breast-implants.

As a measure of our concern for patient safety, it was our Society which took the initiative in 1998, to set up a breast implant registry as a public health measure for improved patient safety. While the idea of a breast implant registry was always sound, its execution has been gradually informed by experience. The PIP situation again underscores the need for reliable international data on breast implants for both cosmetic and reconstructive surgery and we continue to encourage all doctors, surgeons and patients to register their implant details with the existing voluntary and "opt-in" breast implant registry, managed by the Australian Society of Plastic Surgeons, while we pilot our new Breast Device Registry. The new registry incorporates best practice and is designed to be "opt-out" and hence will capture more comprehensive data. We have sought a meeting with the Federal Minister, as soon as possible, to discuss how a more accessible, 'opt-out' Breast Device Registry will improve patient safety and health outcomes and we will therefore seek Federal government funds to ensure equity and access to the registry for all breast implant recipients in Australia.

I trust this has responded to your questions. Please do not hesitate to contact me again if I can be of further assistance.

Yours sincerely
Assoc. Professor Rodney Cooter MB.BS., MD (Adel), FRACS
President

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From: [Removed for confidentiality]
Sent: Friday, 2 March 2012 10:12 AM
To: Debbie Simpson
Subject: Attention: Associate Professor Rod Cooter, President Australian Society of Plastic Surgeons - PIP breast implants
Importance: High

2 March 2012

Associate Professor Rod Cooter
President
Australian Society of Plastic Surgeons

Dear Mr Cooter

As a woman who has had PIP breast implants for 22 months, I am concerned about a number of distressing symptoms that have gotten progressively worse since I had a breast augmentation in March 2010. My symptoms include severe infection and inflammation around both breast implants which required hospitilisation for IV antibiotics. This infection was unusual in that it first appeared more than 1 year after the initial breast augmentation surgery and was located around both breast implants. This breast infection was unable to be resolved despite intensive IV and oral antibiotic treatment over a 6 month time frame. In addition, I experienced breast swelling, pain around the left breast and armpit, extreme hair loss, joint pain and disfiguration, rashes , chronic fatigue, swollen lymph nodes and other symptoms. None of these symptoms were present prior to my breast augmentation in March 2010.

I am aware that there are other Australia women with PIP breast implants who have also reported similar symptoms, some with confirmed ruptures, some without ruptures. The French medical authority (AFSSAPS) has released a report which states that unruptured PIP breast implants experience a phenomenon called silicone gel 'ooze' or gel bleed.

According to the French medical authority, this phenomenon occurs prior to rupture and has caused symptoms in patients which include inflammation to the tissue surrounding the breast implant. Can you please advise why the ASPS has not advised their surgeon members this silicone gel bleed or 'ooze' has been noted in unruptured PIP breast implants and can cause symptoms without rupture.

Women with PIP breast implants are attending consultations with ASPS plastic surgeons and being told categorically that gel bleed is not possible, migration of PIP silicone gel outside the scar capsule is "not possible" and that these womens' symptoms are 'in their head'. These women without ruptures are being told by ASPS plastic surgeons there is no need for removal yet when the implants are removed on the patients' insistence, some are indeed ruptured, others are found to be leaking (without visible rupture), lymph nodes are found to contain silicone and the scar capsule tests are coming back with chronic inflammation and abnormal cells. I have my medical records available as proof that my scar capsules were chronically inflamed and contained synovial metaplasia and macrophages yet I had no obvious rupture. My lymph nodes are also still reactive and enlarged as confirmed by ultrasound, despite my PIP breast implants being removed more than 4 weeks ago. In addition, my plastic surgeon noted that the removed implants had changed colour from transparent (upon implantation) to a opaque milky grey in less than 22 months.

I am a member of a PIP breast implant support group of over 250 members of which the majority have a confirmed rupture (either via ultrasound, MRI or discovery upon removal) and those without rupture are experiencing similar symptoms to myself – namely breast swelling, pain around the left breast and armpit, extreme hair loss, joint pain and disfiguration, rashes , chronic fatigue and swollen lymph nodes. Why are the majority of ASPS members disregarding these symptoms? How can it be a coincidence that so many women with PIP breast implants are experiencing the same symptoms (which can be confirmed by medical records).

I also wish to advise that I have suffered extreme anxiety and stress since the PIP breast implants were recalled in April 2010 due to the conflicting information available from the TGA, ASPS , the European Commission, individual plastic surgeons and media reports. There are a number of ASPS Plastic Surgeons that have announced on their websites that they recommend routine removal of PIP breast implants (without confirmed rupture) which is in direct conflict with the statement on the ASPS website. As a women that has PIP breast implants, I can assure you that I do not want non medical grade silicone inside of me, regardless of whether some future tests deem that these implants are "safe" and the majority of women members of the Australian PIP support group feel the same. I am sure you are aware that most women worldwide feel that removal of PIP breast implants is paramount, as quoted widely in the internal media. Recently the European Health Commissioner John Dalli said he remains "deeply concerned about the potential health impact for women in Europe and elsewhere over the faulty silicone breast implants by French firm Poly Implant Protheses".

It is my understanding that under the Federal Trade Practices Act, women with PIP breast implants should be receiving the removal and replacement of PIP breast implants at no cost to themselves as the PIP breast implant is a faulty product as evidenced by the TGA recall in April 2010. Yet most women are being charged fees between $7,000 and $13,000 to remove and replace these faulty products. A very small minority of ASPS plastic surgeons have agreed to remove and replace at no cost to the PIP patient, another small minority are heavily discounting their fees, yet the majority of ASPS plastic surgeons are charging full fees. Could you please advise why any ASPS plastic surgeons would be charging fees to remove and replace a faulty breast implant?

I would appreciate your earliest reply to the issues outlined above.

Yours sincerely

[Removed for confidentiality]

CHRONOLOGY: ASPS response to PIP situation 2010-2012

When did this happen?	Who communicated?	What was communicated?
Thu, 1 Apr 2010 15:13	CEO to BIR Committee (Callan, Somia)	Email: Confirmation re recall from Stan Racic (Medical Vision Aust.)
Thu, 1 Apr 2010 15:46	CEO to BIR Committee (Callan, Somia)	Email: Media release: AFSSAPS ordered ban on sale of implants
Thu, 1 Apr 2010 18:31	President (Callan) to members	Email: re PIP media report
Tue, 6 Apr 2010 18:35	Dr Larry Kelly (TGA) to ASPS secretariat	Letter: TGA Website notification - silicone breast implants (6 Apr 10)
Wed, 7 Apr 2010	ASPS BIR to patients on Registry with PIP implants: (223 mailed plus 7 no address on file)	Express mail: Copy of TGA notice of 6 April 2010 plus Application form for accessing information held by the registry
Wed, 7 Apr 2010 12:23	President (Callan) to members	Email: Update on communications between ASPS and Government/TGA "1. The ASPS secretariat contacted the TGA Recall Division when work resumed on Tuesday 6 April; 2. The TGA confirmed that they had received a number of calls from consumers, practitioners and interest groups in relation to the recall; 3. TGA wrote to ASPS late Tuesday night and advised that a consumer information update will be available on its website; 4. ASPS secretariat has put the TGA update on the consumer page of the ASPS website; 5. ASPS secretariat emailed a “Member alert” for ASPS members which is also available on the ASPS member website; 6. ASPS secretariat has so far fielded only a small number of emails and calls from patients and members; 7. TGA has not requested that ASPS use the BIR to inform consumers as part of the TGA alert process; 8. The BIR Committee has agreed to use the BIR to contact patients and advise them to contact their surgeon; 9. ASPS issued a media release in relation to the BIR and its value in terms of patient safety."
Wed, 7 Apr 2010 13:58	ASPS media release: website	Media release: Breast Implant Registry for improved patient safety (7 Apr 10).

CHRONOLOGY: ASPS response to PIP situation 2010-2012

When did this happen?	Who communicated?	What was communicated?
Wed, 7 Apr 2010 15:03	ASPS media release: email to members	Media release: Breast Implant Registry for improved patient safety (7 Apr 10).
Fri, 9 Apr 2010 14:13	Breast Implant Registry to ASPS members	BIR Protocol for patients requesting access to information on the Registry. Attachments included protocol and application for access.
Fri, 9 Apr 2010 16:37	Breast Implant Registry to medical device companies (5 known to ASPS: Device Tech, JnJ/Mentor, Allergan, Surgiplas, Medical Device Alliance)	BIR Protocol for patients requesting access to information on the Registry. Attachments included protocol and ASPS privacy statement.
Mon, 19 Apr 2010	ASPS BIR to patients on Registry with PIP implants: (6 mailed) - BIR registration forms received after 7/4/10	Express mail: Copy of TGA notice of 6 April 2010 plus Application form for accessing information held by the registry
Wed, 21 Apr 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Tue, 27 Apr 2010 16:32	Breast Implant Registry Committee to ASPS members	Encourage members to the Younger Fellow on Council (Somia) with any relevant information for collation for the TGA.
Wed, 5 May 2010 16:00	ASPS Councilto members (Perth, WA)	Annual General Meeting: refer to BIR Report to Minister of Health dated (2009) and BIR Committee report to members highlighting PIP.
Mon, 17 May 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Mon, 28 Jun 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Wed, 14 Jul 2010 13:42	Media release: President (Callan) to public.	Website: Media release that "the Breast Implant Registry Committee have issued guidance for women with PIP breast implants. The guidance is consistent with that from other medical organisations around the world."
Wed, 14 Jul 2010 13:42	President (Callan) to members.	Email: With link to website media release and guidance from BIR Committee.

CHRONOLOGY: ASPS response to PIP situation 2010-2012

When did this happen?	Who communicated?	What was communicated?
Thu, 16 Sep 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Thu, 30 Sep 2010 08:40	IPRAS to National societies (ASPS, etc)	The latest information in regard to PIP Implants. Notice that PIP company filed bankruptcy.
Thu, 30 Sep 2010 15:05	ASPS Secretariat to members	Website: Published IPRAS communication from 30/09/2010 8:40:00 AM.
Fri, 1 Oct 2010 11:03	ASPS Secretariat to members	TGA notice published on 1 Oct 2010.
Wed, 6 Oct 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Fri, 15 Oct 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Thu, 21 Oct 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Thu, 21 Oct 2010	ASPS BIR to patients on Registry with PIP implants: (6 mailed) - BIR registration forms received after 19/4/10	Express mail: Copy of TGA notice of 6 April 2010 plus Application form for accessing information held by the registry
Thu, 25 Nov 2010 10:03	ASPS contact DMAC (Adelaide Uni) NJRR	Initial meeting to discuss a Breast Device Registry.
Fri, 3 Dec 2010	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Tue, 8 Feb 2011 14:34	ASPS contact DEPM (Monash Uni)	Initial meeting to discuss a Breast Device Registry.
Thu, 23 Jun 2011 10:08	IPRAS to National societies (ASPS, etc)	Suspension of the decree of the French government PIP
Fri, 8 Jul 2011 16:00	ASPS Council to members (Broadbeach, Qld)	Annual General Meeting: refer to BIR Report to Minister of Health dated (2010) and BIR Committee report to members highlighting PIP.
Fri, 6 Jan 2012	President (Cooter) to Members.	Urge members to compile complete lists of patients from medical files regarding PIP implants for referring to the TGA.
Sat, 7 Jan 2012	ASPS published notice to website.	Breast Information Line. Message from ASPS President.

CHRONOLOGY: ASPS response to PIP situation 2010-2012

When did this happen?	Who communicated?	What was communicated?
Wed, 11 Jan 2012	President (Cooter) to Members.	Request members to send any data from their own records to the ASPS office by return email or as soon as possible.
Fri, 13 Jan 2012	President (Cooter) to Members.	Guidance to simplify the task of data collection sent to members.
Fri, 3 Feb 2012	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Mon, 20 Feb 2012 16:17	ASPS published notice to website.	ASPS President's updated statement dated 20 Feb 2012 re ASPS working with the TGA and information regarding the need for a comprehensive Breast Device Registry.
Mon, 12 Mar 2012 12:09	ASPS published notice to website.	ASPS President's updated statement dated 12 Mar 2012 re Medicare Eligible MRI services, published research, statement on related conditions.
Mon, 26 Mar 2012	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Fri, 20 Apr 2012	ASPS Secretariat to members	Email update: regular email to members with top news and current affairs. PIP identified.
Sat, 5 May 2012 17:30	ASPS Council to members (Kuala Lumpur, Malaysia)	Annual General Meeting: refer to BIR Report to Minister of Health dated (2011) and BIR Committee report to members highlighting PIP.