

Australian Society of Plastic Surgeons Breast Implant Registry

Code of Practice

Breast Implant Registry:

The Breast Implant Registry (BIR), administered by the Australian Society of Plastic Surgeons (ASPS), is a major public health initiative and a declared quality assurance activity¹ under the auspice of the Commonwealth Government Department of Health and Ageing's Qualified Privilege Scheme.

The Breast Implant Registry is of significant benefit to patients, surgeons and to the furthering of medical science. It is critical that processes, administration, security and reporting structures are maintained meticulously.

ASPS complies with all applicable laws and regulations relating to patient information, including all applicable provisions of the Privacy Act 1988 (Commonwealth) and the Health Insurance Act 1973 (Commonwealth).

The BIR is a centralised and secure body of data linking patient, procedure and prosthesis and thus enabling the collection, documentation and analysis of scientific data relating to breast implants.

Registration is voluntary and attracts a nominal fee (levy) paid by the patient of \$25 per implant.

Any data request specific to a particular patient can only be made by that patient, or to a party expressly authorised by that patient. Data requests must be made to ASPS, in writing, and must include proof of identity.

ASPS submits an annual BIR report to the Federal Minister for Health which includes the analysis of de-identified data. This analysis also aims to promote and foster research into breast implants to enhance the existing scientific body of knowledge.

Privacy and Confidentiality:

Any person who, for administrative purposes, is required to access the Breast Implant Registry and/or patient information associated with the Breast Implant Registry must sign a privacy and confidentiality agreement (Form C) which is held at the ASPS Head Office in Sydney.

Security:

ASPS developed a web-based program to enter, manage and secure the BIR data, taking into account the Department of Health and Ageing's mandatory requirements associated with Privilege Status² and ACQSH standards for device registries.

BIR forms are scanned and originals shredded by authorised ASPS staff. Data is backed up nightly and thence a copy to tape for off-site archive.

Data is accessible by authorised personnel via a secure log-in.

¹ The Commonwealth Qualified Privilege Scheme encourages health professionals to undertake quality assurance activities in connection with the provision of certain health services. See

<http://www.health.gov.au/internet/main/publishing.nsf/Content/qps-overview>

² The BIR is a declared quality assurance activity and has been awarded Privilege Status. This status lawfully protects certain information from disclosure and protects persons involved in the activity from civil liability. See

<http://www.health.gov.au/internet/main/publishing.nsf/Content/qps-particip>

Access to a patient's own data is freely available to that patient. Any data request specific to a particular patient can only be made by that patient, or to a party expressly authorised by that patient. By necessity, procedures for authentication of identity are strict. Such data requests must be made to ASPS, in writing (Form A), and must include proof of identity as follows:

Certified copy of:

- birth certificate or
- passport or
- citizenship certificate or
- Medicare Card or
- driving licence or
- a signed letter from the patient's General Practitioner verifying proof of identity.

Process:

ASPS routinely distributes BIR brochures to its member surgeons. Patients sign a Breast Implant Registry consent form provided with the explanatory brochure.

The surgeon, or delegated nursing staff member, completes the form providing patient details, implant history, procedure performed and any other relevant data. A sticker identifying the unique code relating to the implant/s used is also attached to the form. The form is forwarded to the BIR for processing.

Patients notify the BIR of a change of address using a specific form (Form B) which is available from the ASPS office and can be downloaded from the ASPS website.

A \$25 levy per implant from the patient is included within the surgeon's billing for the procedure. This payment is forwarded to ASPS to maintain the BIR, undertake analysis and reporting, and conduct research.

Governance:

ASPS Council maintains a Standing Committee for the BIR. Its membership is: President of ASPS and at least 2 other members of ASPS Council. This Standing Committee may coopt other members or participants as necessary from time to time. ASPS Chief Executive and BIR Manager provide the secretariat function. This Committee meets half-yearly and reports to ASPS Council at least annually.

Financial Reporting:

Australian Tax Office ruled that the BIR levy is exempt from GST. All income derived from the implant payment is used for BIR purposes only.

An independent audit of the financial operation of the BIR is included with the ASPS annual audit and made available in the financial statements to ASPS membership at its Annual General Meeting. The report to the Minister for Health also includes audited financial data.

Insurance:

ASPS maintains the appropriate insurance policies.

Indemnity:

Participation by surgeons in the BIR does not alter their existing obligations in relation to duty of care. Surgeons are responsible for ensuring that patient and device details submitted for registration are accurate.