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### **Australia takes leadership role in patient safety on breast devices**

The Australasian Foundation for Plastic Surgery (the Foundation) is taking a leadership role in the protection of women with breast implant devices, with the launch of a new Breast Device Registry (BDR) designed to capture patient information that will help assess outcomes of individual surgeons and hospitals, and importantly, allow for swift contact with patients should any issues with the devices arise.

Additionally the Foundation is spearheading an international collaborative effort to harmonise data captured by breast device registries around the world.

The Foundation has been jointly established by the Australian Society of Plastic Surgeons and the New Zealand Association of Plastic Surgeons, to provide quality outcomes for everyone involved with plastic surgery. It aims to support excellence, safety and integrity in the field.

“The new BDR is for everyone’s benefit – patients, industry and the Australian Government. Australia is really leading the way with the development of this model so rolling it out is absolutely a top priority for us,” says President of the Australian Society of Plastic Surgeons, Dr Geoff Lyons.

The Foundation’s new Breast Device Registry (BDR) is an opt-out model, incurs no cost to the patient and involves a single form that can be completed by a nurse. The registry is the first of its kind in the world and replaces a previously inefficient model that required extensive paperwork by the patient and payment of a fee. The model, devised in Australia, has already been adopted by the Netherlands.

Around 24,000 – 25,000 Australians receive breast implants each year, but only a fraction were captured on the previous registry.

“When we had to contact the patients affected by the Poly Implant Prothese (PIP) issue in 2010, we discovered our old Breast Implant Registry had only recorded about 5% of all patients – clearly a new system was needed. In 2010 we carried out a scoping study of all successful registries and found none that could answer the questions we were being asked by the Australian Government and the Therapeutic Goods Administration (TGA) as part of the PIP enquiry, so we set about designing a totally new model,” explains BDR chief and plastic surgeon Associate Professor Rodney Cooter.

Founded in 1970, the Australian Society of Plastic Surgeons Inc (ASPS) is the peak body for Specialist Plastic Surgeons (both reconstructive and cosmetic). The Society’s main role is to protect the integrity of plastic surgery as a specialty.



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With the data collected from the Registry, the Society will also be able to monitor re-operation rates of particular surgeons and the infection rates at certain hospitals, leading to a better understanding of breast implant complications.

“Patient safety is our number one priority and with the new BDR we will be able to collect valuable data and inform patients should a problem with their implants arise and also determine just how common breast implant complications are,” says Associate Professor Cooter.

The Foundation has been trialling the new BDR with Monash University at four hospitals across two states, and will officially reveal the initiative at the Society’s Plastic Surgery Congress in Melbourne.

In a world- first, the Foundation is pioneering an international collaboration effort that will harmonise the data collected from different breast implant registries around the world.

Representatives from 15 countries will be at the Plastic Surgery Congress to sign a MoU for the International Collaboration of Breast Registry Activities (ICOBRA), led by the Australian Society.

For the first time, ICOBRA will prepare an internationally comparable minimum dataset to make evidence-based decisions. This is the lesson learned from the PIP Crisis.

“This has never been done before so it’s a very exciting venture to be leading. We are proposing that each country runs its own registry but that we all collect the same points of data. So far the initiative has been very well received by the international plastic surgeon community,” says Associate Professor Cooter, who is also leading the ICOBRA effort.

**For further media information or to interview Associate Professor Rodney Cooter or Dr Geoff Lyons please contact Edwina Gatenby on 0402 130 254 or Shannon Swainston on 0478 053 684**

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