



## The Australasian College of Cosmetic Surgery

*Raising Standards, Protecting Patients*

# MEDIA RELEASE

Urgent - For immediate release

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## **TGA issues breast implant alert** ***Concern over delayed documentation forces*** ***TGA to suspend distribution authorisation***

The Australasian College of Cosmetic Surgery (ACCS) today welcomed the announcement by the Therapeutic Goods Administration that it is suspending authorisation of Cereform breast implants to be used in Australia until concerns about adequate documentation have been addressed.

Cereform breast implants are used relatively uncommonly in Australia. It is estimated that approximately 2,000-2,500 Australian women have been implanted with Cereform implants by Cosmetic, Plastic and other surgeons.

ACCS spokesman Dr Daniel Fleming said the TGA have acted cautiously, as they should, until they and authorities in France, where Cereform implants are manufactured, are completely satisfied that all required safety documentation is up to date.

The documentation concerns centre around sterilisation procedures during manufacture. There appears to be no evidence that the sterilisation process itself has been substandard or ineffective and there have been no reports of increased infection rates with Cereform breast implants.

Dr Fleming said that Australian women who have Cereform implants will understandably be concerned but they should heed the advice from the TGA, which is dealing with the issue in a timely and appropriate way.

“Women with Cereform breast implants, who have not experienced any problems related to infection should be reassured that infection complications would be likely to arise within the first few weeks,” Dr Fleming said.



Women who believe that they have received Cereform implants may also wish to contact their surgeon.

Additional advice and information from the TGA can be viewed here:

<http://tga.gov.au/safety/alerts-device-cereform-breast-implants-140221.htm#.Uwcl1PmSxul>

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**The Australasian College of Cosmetic Surgery** is a multi-disciplinary body of general surgeons, plastic surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other doctors who specialise in cosmetic surgery. The goal of the ACCS is to ensure the safe provision of cosmetic surgery and cosmetic medical procedures to the Australian general community through supply of appropriately trained and certified medical practitioners.