



The Australasian College of Cosmetic Surgery

Raising Standards, Protecting Patients

MEDIA RELEASE

Urgent - For immediate release

25 September 2015

TGA breast implant advisory

The Therapeutic Goods Administration (TGA) has issued an advisory concerning all medical implant devices including breast implants manufactured by Brazilian company Silimed after European regulators suspended the company's conformity or "CE" certificate. Medical devices cannot be marketed in Europe without a CE certificate.

According to the TGA, Silimed's CE certificate was suspended after German health officials inspected Silimed's manufacturing plant and found that the surfaces of some devices were contaminated with unknown particles. The Brazilian manufacturer was inspected in March 2014 and found to comply with all requirements.

Silimed breast implants are used in Australia for cosmetic and reconstructive breast surgery procedures. No adverse events relating to these products have been reported to the TGA, and there has been no indication that these issues would pose a threat to the implanted person's safety.

However, as a precautionary measure and in consultation with the TGA, the Australian distributor has agreed to cease supply of Silimed implants and is contacting surgeons to recommend that scheduled surgeries using Silimed products be postponed.

The TGA is seeking further information from the manufacturer and other regulators and will provide updated information when it becomes available. In the meantime, the TGA is working with professional groups such as the ACCS to provide as much information to patients as possible.

ACCS President Dr Ron Bezic said the TGA has acted prudently, as they should, until they and authorities in Europe are able to clarify the situation.

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

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

<https://www.tga.gov.au/alert/silimed-medical-devices-all-including-breast-implants>

For further information or interviews, contact:

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About the Australasian College of Cosmetic Surgery

Established in 1999, the Australasian College of Cosmetic Surgery (ACCS) is a not-for-profit, multi-disciplinary fellowship based body of cosmetic surgeons, cosmetic physicians, plastic surgeons, general surgeons, maxillofacial surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other doctors and health care practitioners who practice in cosmetic medicine and surgery.

The primary goal of the ACCS is to ensure the safe provision of cosmetic medicine and cosmetic surgical procedures to the Australian community through the supply of appropriately trained and certified health care practitioners. Its Fellows and spokespeople are regularly quoted in the media and consulted by Commonwealth and state health and consumer regulators as authoritative sources of information and expert opinion.

The ACCS is the only medical college which provides education and training leading to fellowship specifically in cosmetic medicine and surgery. Fellows of the College are medical doctors who have completed post-graduate education and training and demonstrated competency specifically in cosmetic medicine and surgery. To become an ACCS Fellow, doctors must typically complete a minimum of 12 years of medical and surgical education and training.

For additional information about the ACCS, please visit: <http://www.accs.org.au/>