Cereform silicone gel-filled breast implants

Safety advisory

The TGA was advised on 13 February 2014 that non-implanted Cereform silicone gel-filled breast implants have been recalled in France after the French regulatory authority, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), found the sterilisation process used in the manufacture of these devices had not been fully validated in accordance with the most recent international standard.

Information from the ANSM states that the French recall is being undertaken because of regulatory non-compliance. They have further stated that they have not identified a health risk associated with this issue.

On 13 February 2014, as a precautionary measure and in consultation with the TGA, the Australian distributor (Medical Vision Australia Plastic & Cosmetic), contacted surgeons who have been supplied with these implants and arranged for any planned implant surgeries to be postponed.

Any further supply of these implants has also been suspended until TGA has finalised its investigation and determined that the implants are safe for use. TGA has sought information from ANSM and from the French manufacturer so that a decision about further supply of these implants can be made. Once this information is received a decision as to whether or not a product recall is required will be made.

TGA has reviewed its records and has contacted surgeons who have implanted these products and has not identified any evidence that would suggest a problem with the sterility of these implants.

TGA is discussing the issue with the relevant professional societies.

Cereform breast implants are manufactured in France by Cereplas. The ANSM undertook the French recall of non-implanted product after an inspection of the manufacturing facility determined that the validation of the sterilisation process was not consistent with the requirements of the current international standard. Cereplas had made a commitment to address the issue by the end of 2013, but this commitment was not fulfilled. The manufacturer's CE certificate to manufacture the device was suspended on 10 February 2014 pending resolution of the issue identified by ANSM.

Information for consumers

If you have received a Cereform breast implant and did not experience an infection soon after the surgery, then you should not experience any problems associated with this issue. An infection would be recognised by localised pain at the site of the implant and possibly an increase in body temperature.

If you have any questions or concerns about this issue, contact your general practitioner or surgeon for individual clinical assessment and advice.

Information for health professionals

If you have a patient who has received a Cereform breast implant, be alert to the issue and the potential complications for patients.

Reassure them that if they were going to experience an infection related to this issue, it would occur in the immediate post-operative period.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices. Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.