



Information for consumers

What you need to know about unapproved breast implants

The following information is for a consumer whose health practitioner is intending to apply through the Special Access Scheme to use an unapproved breast implant device for their surgery. This information aims to help you make an informed decision about whether you want to have an unapproved breast implant device implanted.

Medical devices must be evaluated for quality, safety and performance and included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. A medical device that is not included in the ARTG is known as an 'unapproved device'.

All breast implants available in Australia recently underwent a thorough assessment due to concerns about some implants being linked to Breast Implant Associated Anaplastic Large Cell Lymphoma, or BIA-ALCL. As a result, a number of breast implants were suspended or cancelled due to concerns about overall safety and performance of the implants, as well as the associated risk of BIA-ALCL. This means they were removed from the ARTG and cannot currently be legally used in Australia without special approval.

What is the Special Access Scheme?

The Special Access Scheme allows health professionals to access unapproved medicines and medical devices for their patients, on a case by case basis.

It is expected that your health practitioner will have considered all of the alternative options on the ARTG, and have appropriate clinical reasons for considering unapproved breast implants for you under the Special Access Scheme.

Your health practitioner is required to apply to the Therapeutic Goods Administration (TGA) through the Special Access Scheme in order to supply an unapproved breast implant for use in your breast implantation surgery. You should be provided details of the name of the device and when it was suspended or cancelled from the ARTG.

Understanding the risks

Your health practitioner should explain to you the reasons why they want to implant an unapproved device in you instead of an alternative approved device.

Recently your health practitioner has received additional safety information published by the TGA regarding the suspended breast devices. This information can be found at www.tga.gov.au/alert/update-safety-and-performance-concerns-suspended-breast-implants. We suggest you discuss this information with your health practitioner and ask about options and alternatives.

To support informed patient choices, all breast implant devices must be supplied with a patient information leaflet that includes information about warnings and risks associated with the product. Your health practitioner should give you the patient information leaflet to consider prior to you making a decision about your procedure.

Australian Breast Device Registry

The [Australian Breast Device Registry \(ABDR\)](http://www.abdr.org.au) collects information about breast implants to support ongoing reporting and monitoring of adverse events, including BIA-ALCL.

The Australian Government established the ABDR to track the long-term safety and performance of breast implants as well as identify best surgical practice to help safeguard health outcomes for patients.

The TGA encourages you to contribute by participating in the ABDR. Research reports and other publications that use ABDR data will not contain any identifiable information about you. More information is available on the ABDR website at www.abdr.org.au.

For further information about breast implants go to the TGA Breast Implant Hub at www.tga.gov.au/hubs/breast-implants