



## Information for health professionals

# Update on safety and performance concerns of suspended breast implants

28 November 2019

*This information sheet provides more detailed information about the technical nature of the Therapeutic Goods Administration (TGA) assessment against the international standards relevant to breast implants.*

On 9 April 2019, the Therapeutic Goods Administration (TGA) commenced a post-market review of breast implants in response to the increasing number of cases of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

On 25 September 2019, a decision was taken to suspend eight entries (see table below), from four manufacturers, from the ARTG for a period of six months, commencing from 25 October 2019. General information about the decision is available on the TGA website, including information for consumers.

Sponsors of breast implant devices supplied in Australia were required to provide samples for laboratory analysis and documentation about their manufacturing processes, risk management strategies, clinical evidence, and biological safety assessments.

To assist in determining the risk/benefit profile of each of the implants, the TGA considered the estimated risk rate of developing BIA-ALCL using case information and supply figures to determine the statistical correlation for both last implant and single implant data. In addition, the TGA Laboratory's detailed assessment of implant surface texture and comparative mapping of surface texture was also considered, along with claims of equivalence of the surface texture and manufacturing process, made by the manufacturer in their documentation, to other breast implants.

In the case of the suspended devices, Nagor, Groupe Sebbin, and Eurosilicone all claimed technical equivalence to the Allergan macrot textured devices, which have been cancelled from inclusion in the Australian Register of Therapeutic Goods (ARTG) by Allergan in August 2019. Polytech Health & Aesthetics

GmbH claimed technical and biological equivalence to Silimed polyurethane-coated implants, which have been cancelled from inclusion in the ARTG by the TGA in November 2016. The cancelled devices currently have the highest risk rate of BIA-ALCL in Australia.

A [detailed report of the laboratory analysis](#) was published on 26 September 2019.

When reviewing the information provided by the sponsors and manufacturers, compliance with the Essential Principles was assessed, with reference to TGA guidance documents, as well as several international standards. The Essential Principles are a set of 15 principles that all medical devices in Australia are required to hold evidence of compliance against, before the TGA provides approval to supply in Australia. The Essential Principles relate to safety and performance of medical devices, the details of which can be found on the [TGA website](#).

In relation to specific guidelines and international standards taken into account, these include:

- [Clinical evidence guidelines: medical devices](#)
- ISO 14607:2018 non-active surgical implants – mammary implants – particular requirements
- ISO 10993:2018 biological evaluation of medical devices
- ISO 14971:2007 risk management for medical devices

Advice from an expert working group, clinicians, consumer groups, and patients was sought. The TGA considered feedback in relation to complications including capsular contracture and the use of certain implants in reconstruction surgery.

The TGA identified a number of deficiencies in the evidence submitted by sponsors and manufacturers to demonstrate an acceptable level of safety and quality of the materials used and/or the long term effects of the implants in the body. Specifically, the TGA was concerned that there was insufficient evidence to demonstrate compliance with ISO 10993:2018 biological evaluation of medical devices.

For each implant, the TGA assessed the sponsor's and manufacturer's documentation against ISO 10993:2018 including:

- Evidence of implantation assessments (e.g. did not result in swelling or persistent inflammation in the body)

- Evidence of reproductive toxicity (e.g. did not result in harm to reproductive organs or fertility or affect offspring)
- Evidence of carcinogenicity (e.g. did not cause cancer)
- Evidence for immunotoxicology testing (e.g. did not harm, or elicit an altered response from, the body's immune system).

Sponsors have six months to address these deficiencies (ie: until 24 April 2020). If the deficiencies cannot be remedied, the TGA may make a regulatory decision to cancel the devices from the ARTG.

An outline of the TGA identified concerns are detailed below.

Sponsor (manufacturer)	ARTG number	Product name	Safety and performance concerns
Allied Scientific Products Pty Ltd (Nagor)	142863	Nagor Mammary Implants Gel-filled-TEXTURED	<p>The following safety and performance concerns were identified that relate to ISO 10993:2018:</p> <ul style="list-style-type: none"> <li>• gaps in the implantation assessment</li> <li>• gaps in reproductive toxicity and carcinogenicity testing</li> <li>• gaps in immunotoxicology testing.</li> </ul>
	277757	9-cell CoGel gel-filled Nagor mammary implant range - textured	
	277758	Impleo gel-filled Nagor mammary implant range - textured	
Emagin Pty Ltd (Groupe Sebbin SAS)	309613	Anatomical Breast Implants - Textured - High Cohesive Gel	<p>The following safety and performance concerns were identified that relate to ISO 10993:2018:</p> <ul style="list-style-type: none"> <li>• insufficient evidence to support biological safety, specifically assessments of reproductive toxicity and carcinogenicity</li> <li>• gaps in immunotoxicology testing</li> <li>• gaps in implantation evaluation</li> <li>• gaps in cytotoxicity evaluation.</li> </ul>
Euro Implants Pty Ltd (Eurosilicone SAS)	132040	Cristaline I Aptex/Vertex Paragel Natural Cohesive Gel Implant	<p>The following safety and performance concerns were identified that relate to ISO 10993:2018:</p> <ul style="list-style-type: none"> <li>• absence of carcinogenicity testing</li> <li>• absence of immunotoxicology testing</li> <li>• absence of implantation assessment</li> <li>• absence of reproductive toxicity testing.</li> </ul>
	132037	Cristaline Paragel Cohesive Gel Implant	

Sponsor (manufacturer)	ARTG number	Product name	Safety and performance concerns
JT Medical Pty Ltd (Polytech Health & Aesthetics GmbH)	171782	Sublime Line, Microthane, Silicone gel filled Mammary Implants	<p>The following safety and performance concerns were identified that relate to ISO 10993:2018:</p> <ul style="list-style-type: none"> <li>• absence of evidence relating to the risk of chronic-active tissue response, reproductive toxicity and carcinogenicity</li> <li>• insufficient evidence of immunotoxicology testing</li> <li>• insufficient evidence relating to biodegradation.</li> </ul> <p>Further to these concerns, the claimed benefits of the highly textured surface of the device was not supported by the manufacturer's evidence.</p>
	185060	4Two Line, Single Lumen, Micro Polyurethane, Silicone gel filled Mammary Implants	

On 25 September 2019, stringent reporting and patient information conditions were imposed by the TGA on ALL breast implant devices remaining on the ARTG.

A decision was taken not to suspend the Johnson & Johnson (Mentor) devices on the basis of the clinical benefit outweighing the safety concerns. This decision was based on the TGA's assessment that deficiencies in the risk management framework and outdated biocompatibility testing of the Mentor devices could be addressed through the imposition of additional conditions. In addition, it should be noted that the suspended devices have more significant gaps in the biological evaluation data and a much increased estimated risk rate of BIA-ALCL compared to the Mentor devices.

During the course of the review some of the devices were also assessed for particulate contamination. This work is still on-going; updates will be provided on the TGA website as they become available.

## More information

- Biomaterials and Engineering Laboratory Report: Non-active mammary implants: <https://www.tga.gov.au/biomaterials-and-engineering-laboratory-report-non-active-mammary-implants>
- Essential principles checklist (medical devices): <https://www.tga.gov.au/biomaterials-and-engineering-laboratory-report-non-active-mammary-implants>
- Clinical evidence guidelines: Medical devices: <https://www.tga.gov.au/publication/clinical-evidence-guidelines-medical-devices>