



A statement by The British Association of Aesthetic Plastic Surgeons (BAAPS) on the withdrawal of Allergan (Natrell®) textured implants

19th December 2018

BACKGROUND

Over recent years, plastic surgeons have become aware of and studied a known link between breast implants that have a textured surface and the condition Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

BIA-ALCL is rare and, usually, eminently treatable. Current research suggests the risk of developing this condition in the UK is approximately 1 in 24,000 breast implants sold. For comparison the general incidence of breast cancer in the UK is 1 in 9 and affects women with and without breast implants equally. More guidance on BIA-ALCL can be found [here](#).

Not all textured surfaces are manufactured in the same way and they appear to convey different levels of risk, hence it is difficult to draw definite conclusions at this time. Texturing of an implant surface also offers advantages, particularly with more anatomically shaped implants. Hence many surgeons in the UK still advocate the use of textured implants for their patients. It is vital however, that the risks of using textured or smooth surfaced implants are fully discussed with all patients prior to surgery so that patients are able to make informed choices.

Several different companies manufacture breast implants for both aesthetic and reconstructive use. These implants can have different types of texturing on their surface and some research has indicated that BIA-ALCL might be related to a particular type of texturing or manufacturing processes. One major company, Allergan, produces implants known as Natrell® with a surface called Biocell®. These implants are available worldwide but can only be sold under licence.

In Europe, all medical devices are regulated and must have a stamp of safety or licence. This is known as a CE mark. All manufacturers are periodically required to apply for re-certification of their CE mark to continue to supply their devices for patient use.

THE CURRENT SITUATION

Due to concerns over the possible link with Allergan's textured surface (Biocell®), the CE mark has not been re-awarded for this product. Hence from late December 2018, Allergan's textured implants are no longer available for patient use. This is a precautionary measure until more data becomes available and Allergan continues to work with the authorities to clarify the issue. The BAAPS has advised its member surgeons not to insert Allergan textured implants from today.

The CE mark for Allergan's smooth surfaced implants has been renewed and their smooth implants are not affected. The failure to renew the CE mark for their textured implants does not at this stage affect any other manufacturer.

GUIDANCE FOR PATIENTS

The British Association of Aesthetic Plastic Surgeons advises that concerned patients need not take



any action at this stage. They should continue their routine follow up with their healthcare professional and discuss any questions they have about their breast implants. There is no need to remove or exchange any current implants based on the most up-to-date scientific data available. Indeed, unnecessary surgery may cause additional harm in a small number of patients.

Paul Harris, President of The British Association of Aesthetic Plastic Surgeons stated: “The news that Allergan’s CE mark for their Biocell® textured surface implants has not been renewed will be a cause for understandable concern for many patients, particularly those who have implants currently in place. It is important however to recognise that this is a pre-cautionary step taken by the regulators whilst the link between breast implant surface and BIA-ALCL becomes clear.” He continued, “We advise any patients with new symptoms such as swelling or pain to contact their implant surgeon for specific advice, otherwise they should make a routine appointment when available to discuss their concerns”.

Marc Pacifico, BAAPS Council Member and Consultant Plastic Surgeon commented: “The majority of patients in the UK with breast implants will have textured surface implants in their breasts. According to all the latest scientific data these remain safe devices and there is no indication for any woman to consider removing or replacing their implants. Patients should continue with any planned follow-up they have arranged.”

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