**INSERT DATE**

Dear

**RE: Allergan implants**

You may have read in the media that the CE mark for Allergan Biocell textured implants has recently not been reinstated, although these implants are still approved for use elsewhere in the world outside of Europe.

Allergan breast implants are regulated in Europe by a Notified Body in France. On a periodic basis, like all medical device manufacturers, Allergan is required to submit for renewal of its CE mark to manufacture and supply its implants. The routine review and renewal of Allergan’s CE mark for its Biocell textured breast implants has not yet been completed by the authority that awards the CE mark. This non-renewal is not based on any new scientific evidence nor has the authority identified any immediate risk to the health of women with textured breast implants.

However, there is a rare relationship between textured breast implants and a type of lymphoma (a cancer that begins in infection fighting cells of the immune system) that can occur in the tissue surrounding an implant. This is called breast implant associated anaplastic large cell lymphoma (BIA ALCL).

The risk of this occurring is estimated to be 1 in 27,000 patients who have a textured silicone breast implant. This is a very small risk compared to the risk of developing a breast cancer, which is 1 in 8 women.

The risk of BIA ALCL has been reported to be slightly higher with Allergan textured breast implants. This may be because of the way they are textured, although there could be many other factors Allergan breast implants are the most widely used implants in the world and have always been labelled since first-ever production, meaning they can always be identified. This may be one of the reasons why it appears that they may have an increased risk.

The current advice is that there is no need for concern if you have an Allergan implant, and there is no reason for its removal. All patients should be breast aware. If it does occur BIA ALCL usually presents with a fluid swelling around the implant (known as a seroma). This can be at around six to seven years post breast augmentation. The condition is very treatable involving removal of the implant and the surrounding tissue.

Should you have any further concerns please do not hesitate to contact us.

Yours sincerely

***INSERT NAME***

***Consultant Breast Surgeon***