

Dublin, 4 December 2020

For the Attention of the SCHEER Committee

Please find our response to **Point 2**

## **Point 2**

In this conclusion a statement was made that there is “moderate” evidence for a “causal” relationship between textured breast implants and BIA-ALCL. Although there is substantial clinical literature confirming that breast implants are associated with an increased risk of ALCL, Fitzal *et al* (2019) discusses that despite there being many studies looking at BIA-ALCL and its causes, it is not possible to estimate the risk of BIA-ALCL as there is not enough available data. Sundfield *et al* (2019) also states that it is unclear what the underlying pathogenesis and mechanisms are for BIA-ALCL. Finally, Prantl *et al* (2020) supports this view point also stating: “The rarity of the disease along with insufficient data on women with breast implants and breast implant sales contributes to insufficient statistical information”. Breast implants are also not the only denominator in the development of ALCL in the breast (Sundfield *et al*, 2019). In 2019, Bergsten *et al* presented a rare case of primary cutaneous ALCL of the breast in a patient with no known history of breast implants discussing that, as with any cancer, ALCL can present without any known implant cause.

Without any definite knowledge of the pathology or aetiology GC Aesthetics would therefore state that until the pathogenesis of BIA-ALCL is known, they would contend the overall risk as low and a causal relationship, albeit moderate cannot be substantiated.

## **References**

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Fitzal F, Turner SD, Kenner L. Is breast implant-associated anaplastic large cell lymphoma a hazard of breast implant surgery? Open Biol 2019 9:190006

Prantl L, Gerken M, Zeman F, Leitzmann M, Koller M, Klinkhammer-Schalke M, Evert M, Kuehlmann B, Biermann N. Incidence of Anaplastic Large Cell Lymphoma and Breast-Implant-Associated Lymphoma—An Analysis of a Certified Tumor Registry over 17 Years. J. Clin. Med. **2020**, 9, 1247; doi:10.3390/jcm9051247

Sundfeld D, Real S, Resendes B. Breast implant-associated anaplastic large-cell lymphoma: a systematic literature review. Rev. Bras. Cir. Plást. 2019;34(4):531-538