ANSWERS TO THE ICIJ

IMPACTS ON HEALTH

Health authorities around the world have already recognized the anaplastic large cell lymphoma (BIA-ALCL) associated with breast implants.

Studies have found the highest BIA-ALCL rates on women with textured implants.

A large number of women also started to report a breast implants illness which can turn out to be of an autoimmune nature. There are already more than 50,000 patients in a Facebook group page dedicated to discuss this issue

1) What is the position of Silimed in relation to BIA-ALCL and the safety of textured implants?

2) And what does the company think about this illness caused by breast implants?

Answer 1 – Silimed fully supports ongoing research into all reports of side effects, and Silimed has cooperated with multiple government-initiated safety studies and investigations.

Another reality that deserves to be discussed is that this is a rare disease. For example, if we consider that the risk of BIA-ALCL development is 0.003% (1 in each 30,000 patient group), according to the FDA, compared to a woman's risk of developing breast cancer (12.5%, or 1 person to each group of 8), we will find that it is undeniably rare.

We can also report that, statistically, there is not conclusive studies that textured implants present a greater relationship with the onset of the disease. For this reason, we do not consider correct the generalization that implants of this nature are causing BIA-ALCL.

Either way, we have developed a strict post-sales follow-up process. Through a Complaints Committee, we receive all the demands of medical professionals and clients, and then we evaluate each case separately, whatever may the reason for the complaint be. The committee is a high technical level group of people, including doctors-consultants who meet with professionals from other sectors of the company in search of the best answers to patients. Silimed also supports fully informed decisions by patients, as per the Instructions for Use provided by Silimed to its customers (surgeons and clinics).

Answer 2 –"Breast implant illness" cannot be considered a medical diagnosis.

The relationship between silicone breast implants and autoimmune or connective tissue diseases has been studied for many years by renowned scientists and authorities. According to the FDA's update on the safety of silicone gel filled breast implants, it is important to note that the Washington-based Institute of Medicine (IOM) released a comprehensive report on the literature published and on ongoing studies on breast implants, entitled "Safety of Silicone Breast Implants". This report concluded that there was no conclusive evidence that silicone breast implants are causing systemic health effects.

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SILICONE NuSil

- European regulators have detected a batch of contaminated silicone in Silimed implants in 2009, produced by NuSil.

1) How many Silimed implants in 2009 had NuSil silicone, and until when did the Silimed implants had silicone from that manufacturer?

2) In which countries did Silimed sell these implants?

3) What quality parameters does Silimed currently use to monitor allowable levels of contamination in silicone, including cyclic siloxanes purchased from NuSil or from other suppliers?

First of all, we would like to clarify that it is absolutely wrong to state that contamination was detected in that batch of Silimed implants. This is not true. According to the standards in effect at that time, our raw material was fully fit to the market, including a 40% lower rate than the international standard for implantable breast implants (ASTM F703-07).

What had been detected at the time was the presence of siloxanes, a volatile chemical compound that is an integral part of the silicone feedstock. That is, it has no relation with any contaminating substance. As an additional explanation, we can guarantee that the very presence of siloxanes was absolutely within the provider specification, including a rate 40% lower than the rate required by the international standard.

In only a single sample of the Silimed a siloxanes question was raised. But, in fact, the truth is that it was an old and expired sample, manufactured in 2009, and that should not have been analyzed. The expired sample was in compliance with raw material specification at that time.

Answer 1 - All of our products had Applied silicone that year. Since 1988, when the raw material supplier was Applied, and until today, with NuSil (which eventually took over from Applied).

Answer 2 - Silimed has sold implants in about 75 countries, complying with the standards, certifications and technical and legal requirements determined by the control and monitoring agencies of the different markets.

Answer 3 - The quality parameters used by Silimed are defined by the public health authorities of the countries where we operate. All our batches of products are monitored with extreme care and professionalism.

In Brazil, all of our production is evaluated annually by Inmetro (National Institute of Metrology, Quality and Technology), which is an executive agency linked to the Ministry of Development, Industry and Foreign Trade. We also invest in the continuous qualification of our suppliers, which contributes to the efficiency of monitoring the quality, safety and efficiency of Silimed products.

It is worth noting that in 2012, raw material suppliers, including Applied (now NuSil) further reduced the specifications that regulate the siloxane level, increasing the safety and efficiency of a product that has always presented undisputed quality in the main markets of the world.

TECHNOLOGICALLY PRODUCED MINERAL FIBERS

- SIlimed has produced implants with MMMFs from 2009 to 2015.

1) In which countries have Silimed implants with MMMF been used after 2015?

Initially, for clarification, it is necessary to inform that have microscopic particles present in any environment other than vacuum, and are inherent to the manufacturing process of this type of product. Controlled environments and "clean rooms" offer efficient air quality control. This, however, does not mean absolute absence of particles. Thus, it is necessary to make it clear that all medical devices have microscopic particles on their surface, and it is not correct to say that this fact adds significant risk to patients.

A United States-based high-profile and independent laboratory, titled NAMSA, performed particle analysis on silicone breast implants and compared implants from four companies competing with Silimed. The results revealed that particles were present in all implants evaluated, and that the volume of particles present in Silimed impants was similar and in some cases even lower than the number of particles present in implants of the competitors.

Answer 1 – Silimed implants were used in countries that integrate our business portfolio. And always in strict compliance with the regulations, certifications, requirements and specific laws of the health authorities. It is not possible to market this type of product without the authorization of the local health authorities, who are increasingly demanding regarding the safety of patients.

REGULATION

- The FDA has announced it will hold a public hearing on the safety of breast implants in 2019. This was decided after a meeting with patient advocates who demanded stricter regulation of breast implant procedures.

1) Does SIlimed believe that additional regulatory measures are necessary to protect women's health in the US, Europe and Brazil?

2) Should breast implants include a "controlled substance" label that works as an alert to patients?

Answer 1 - Market monitoring is extremely important for the maintenance of the global regulatory system in sectors that are related to the health and well-being of the population. Through this monitoring it is possible to verify the frequency and the occurrence of risks of the procedures, including possible side effects.

This after-sales service should be a commitment of all the companies that work in the health and wellness products sector.

Within this context, Silimed complies with all regulatory requirements for after-sales, proceeding with the monitoring according to the regulations of ANVISA (Brazil), ISO 13485: 2016 and the countries in which it markets its products. In this way, we seek to actively and preventively contribute to the improvement of our products and processes, as well as the improvement of the regulatory system as a whole.

Answer 2 - It is important to remember that breast implants, as well as implants used in other areas, are products aimed at the medical community and are not made to be sold directly to patients. Because they are products that require surgical intervention, the responsibility to inform patients about the benefits and risks must be with the health professional, together with the companies that produce and market them.

In relation to the proposal to use a “controlled substance” label on the product, we consider that this type of alert works more specifically when adopted in medicines and other products that can be purchased directly by the consumer, without necessarily having the direct action of a qualified medical professional.

In the case of implants, practical effect of the vast majority of patients who receive, for example, a breast implant do not have access to the package that protects the product. these are sent directly to the hospital or clinic of the health professional, and properly discarded after the procedure.

In view of all the above, it is essential that the doctor-company and doctor-patient relationship be as honest and transparent as possible, so that all information that the professional needs is made available by the company. In this way he can offer patients information with clarity and security.

Last, but not least, we note that all expected side effects information is described in the product’s instructions for use, which must be delivered by the physician to the patient. The instruction for use is one of the forms of consultation and alert to the patient, since it is elaborated from scientific references recognized and approved by the regulatory authorities.