POLYTECH

Dieburg, 04. April 2019

Sehr geehrte Chirurginnen und Chirurgen,

ich wende mich an Sie in meiner Funktion als CEO von POLYTECH Health & Aesthetics. Wir sind der einzige deutsche Hersteller von Brustimplantaten mit über 30 Jahren Erfahrung auf diesem Gebiet.
Wie Sie wissen, hat die französische ANSM ihren Beschluss veröffentlicht, mehrere Implantate willkürlich zu verbieten, die nach ihrer eigenen Klassifizierung als makrotexturiert eingestuft werden und zur Zeit in Frankreich vertrieben werden. Das Gleiche gilt für mit Polyurethan beschichtete Implantate.

Diese Entscheidung betrifft unsere POLYtxt®- und Microthane®-Implantate, die Teil eines breiteren Spektrums von Brustimplantaten sind, die wir Chirurgen und Patienten anbieten, um allen klinischen Bedürfnissen gerecht zu werden. Unsere Produkte POLYsmoooth® in runder Form und MESMOsensitive®, die weiterhin in runder und anatomischer Form verfügbar sind, sind von der französischen Entscheidung nicht betroffen. Außerhalb Frankreichs sind alle unsere Produkte jederzeit lieferbar und können ohne Einschränkung verwendet werden.

Noch wichtiger ist jedoch, dass diese Entscheidung Auswirkungen auf Chirurgen und Patienten hat, indem sie die Anzahl der auf dem französischen Markt verfügbaren sicheren Produkte begrenzt und Implantate, die effizienter sind und die niedrigsten Komplikationsraten aufweisen, von der Verwendung ausschließen.

Hinzu kommt, dass auch wenn die ANSM die prophylaktische Entfernung der bereits implantierten texturierten und mit Polyurethan beschichteten Implantate weder empfohlen noch vorgeschlagen hat, diese Entscheidung Frauen höchstwahrscheinlich weltweit dazu veranlassen wird, sich unnötigen Operationen zu unterziehen und sich den zusätzlichen Risiken, die sich daraus ergeben, auszusetzen.

POLYTECH widerspricht der Entscheidung der ANSM ganz entschieden, da diese Entscheidung auf keinerlei wissenschaftlicher Grundlage basiert und keine Transparenz aufweist. Sie ist auch nicht nachvollziehbar, da einige Anbieter mit maxcro-texturierter Oberfläche laut französischer Klassifizierung der Oberflächen nicht aufgeführt werden. Unser Unternehmen wird die notwendigen Schritte unternehmen, um die Entscheidung vor der zuständigen Justizbehörde formal anzufechten. Dies geschieht, da wir zuversichtlich sind, dass diese Entscheidung aufgehoben werden wird.

Auch möchten wir darauf hinweisen, dass es sich bei den aufgetretenen Fällen von BIA-ALCL mit Polyurethanbeschichtungen fast ausschließlich um Produkte eines ehemaligen Mitbewerbers aus Brasilien handelt, die sich von unseren Produkten nicht nur in der Herstellung unterscheiden. Laut den publizierten Zahlen eines der größten Hersteller weltweit, ist das Risiko bei den von POLYTECH hergestellten Polyurethan beschichteten Implantaten um fast die Hälfte geringer.

POLYTECH

Auf Grundlage unseres kürzlich erneuerten CE-Zeichens, das die Qualität, Sicherheit und Leistungsfähigkeit unserer Fertigungsprozesse und aller unserer Produkte bestätigt, werden wir weiterhin unser gesamtes Sortiment an Brust- und Körperkonturimplantaten herstellen. Dieses beinhaltet ebenso unsere POLYtxt®- und Microthane® Brustimplantate, die weiterhin in alle Länder vertrieben werden, außer in Frankreich.

In der Zwischenzeit haben wir uns bei POLYTECH im Rahmen unserer Verpflichtung zur Sicherheit dazu entschlossen, über Fachverbände Chirurgen weltweit zu kontaktieren und transparente, medizinisch fundierte Informationen über die aktuellen Umstände, die hohe Sicherheit und Leistungsfähigkeit unserer Produkte, sowie zum Thema BIA-ALCL im Allgemeinen verstärkt zur Verfügung zu stellen.

Ein noch umfassenderer Informationsaustausch zwischen Herstellern und Chirurgen ist der Schlüssel zu „good practices“ und insbesondere zur Bereitstellung umfassender und klarer Informationen für Patienten, damit diese eine wirklich informierte Einwilligungserklärung abgeben können.

Wir danken Ihnen für Ihr Vertrauen und Ihre Aufmerksamkeit. Wir stehen Ihnen jederzeit für weitere Informationen und im Falle von möglichen Zweifeln gerne beratender und aufklärender Form zur Verfügung.

Ihr

Wolfgang Steimel, CEO
POLYTECH Health & Aesthetics GmbH

POLYTECH

IMPLANTS BY POLYTECH: HOW AND WHY WE ARE DIFFERENT

POLYTECH is the only German manufacturer of breast implants. Our production process is entirely based in Dieburg, near Frankfurt. All our products are CE marked, and our breast implants fulfilled the higher requirements of CE marking as Class III devices even before breast implants were included in this Class.

As a Manufacturer of an implantable device, we are aware of our responsibility, and we offer products that are safe and performing. We continuously invest in innovation and safety, and our products not only meet, but consistently exceed the requirements set by ISO standards for the manufacturing of mammary implants.

Our breast implants are available with four different surfaces: the smooth POLYsmoooth®, the two textured surfaces MESMO*sensitive*® and POLYtxt® and Microthane®, covered with a micropolyurethane foam.

We recently broadened our range by including the B-Lite® implants, that thanks to the special microspheres that enhance their gel-filling, are up to 30% lighter than the traditional implants. B-Lite implants are currently available in our smooth and textured surfaces, and will soon be available also in combination with our fine-textured and PU-covered surfaces.

Following, please find important information on the safety and performance profiles of our surfaces.

MICROTHANE®

POLYTECH's polyurethane covered implants, or PU-implants, are patented, and registered under the trademark Microthane®.

According to all the indexed literature (most recently, Atlan *et al*., 2018; Hamdi, 2019), the PU foam that covers the implant surface is a three-dimensional matrix that has a specific and very different mechanical and biological interaction with tissue, an interaction that is not comparable with textured implants.

Szycher (1991) explains this interaction very clearly: "*The thin (1.5-2mm) polyurethane foam architecture interacts with breast tissue and help prevent tissue hardening by encouraging surrounding fibroblasts to ingrow into the porous foamandsynthetizecollagen denovo, facilitating anuncompacted, richly vascular capsule around the implant. It is the nature of this tissue interaction with the polyurethane fibers which is the key in preventing capsular contracture*".

A vast literature documents the positive safety and performance profiles of PU covered implants. Extensive clinical studies over the past fifty years, reviewing large numbers of patients[1], have shown the low complication rates and positive outcomes achieved by using PU-covered implants. The following results stand out:

	Smooth implants	Textured implants	PU-covered implants
CC* rate	30-50%	15-30%	0-9%
* CC = capsular contracture.			

[1] As an example, Ashley, 1972; Eyssen, 1984; Hermann, 1984; Schatten, 1984; Pennisi, 1985; Hester *et al*., 1988; Baudelot, 1989; Shapiro, 1989; Pennisi, 1990; Handel, 1991; Szycher, 1991; Gasperoni *et al*., 1992; Vazquez, 1999; Hester *et al*., 2001; Handel, 2006a; Handel 2006b; Vazquez, 2007; Rancati, 2013; Castel *et al*., 2015.

In most of the large studies, the rate of CC with PU-covered implants is as low as 0-3%. A lower rate of late seroma was found (Vazquez, 2007) too, late seroma being known today as a symptom of a possible BIA- ALCL.

Furthermore, clinical studies focusing specifically on POLYTECH's Microthane® implants confirm that these implants offer actual benefits to patients, both in augmentation surgery and in reconstruction surgery (Pompei *et al*., 2016; Pompei *et al*. 2017).

For patients with capsular contracture, or even with a history of recurring capsular contracture, PU- covered implants are often the only solution. As a replacement, if properly implanted to allow the creation of a new capsule, PU-covered implants are the go-to solution to spare the patients from further pain and re-operation risks.

POLYTXT® AND MESMO*SENSITIVE*®

Implant surfaces are textured according to different manufacturing processes. While most manufacturers use the salt loss technique, which consists in embedding sodium chloride crystals in the surface of the shell, covering them with additional silicone and, after vulcanization, washing or brushing them away, the POLYtxt® and MESMO*sensitive*® surfaces are textured by vulcanization of the shell, which causes the thermal decomposing of ammonium carbonate salts and generates no sharp edges or particles. Such different texturization methods have of course different implications, that reach beyond the mere structure of the texture but concern also the forces the shell is subject to, and the possible formation of particles.

The POLYtxt® and MESMO*sensitive*® surfaces are much finer and very different than the Biocell surface.

Manufacturer	Surface	Roughness (Sa/µm) acc. Barr *et al*. 2017/ Jones *et al*. 2018/ University of Darmstadt
Allergan	Biocell	80 / 92 / -
Polytech	POLYtxt®	42 / 59 / 43
Polytech	MESMO*sensitive*®	- / - / 24

THE ISO 14607:2018 TEXTURE CLASSIFICATION

The International Organization for Standardization is an independent, non-governmental organization. The use of the standards aids in the creation of products and services that are safe, reliable and of good quality, ensuring that certified products conform to the minimum standards set internationally. The ISO 14607:2018 standards for mammary implants define as micro-textured the surfaces with an average roughness between 10 and 50 µm. Therefore, both textured surfaces by POLYTECH – POLYtxt® and MESMO*sensitive*® – are micro-textured surfaces.

SAFETY OF POLYTECH PRODUCTS

POLYTECH products are manufactured in Germany from implantable grade silicone. Each implant is subject to control at every stage of production. Tests on our implants show results that not only meet, but remarkably exceed the minimum requirements of ISO standards.

In July 2016, concerned with BIA-ALCL, the ANSM required manufacturers to perform additional product biocompatibility testing. Subsequently, all of the four POLYTECH implant surfaces, were tested in accordance with EN ISO 10993 by the independent institute BIOSERV Analytik und Medizinprodukte GmbH. Completed in March 2018, the tests found no increased risk of BIA-ALCL with any of the four POLYTECH implant surfaces.

The following table summarizes the BIA-ALCL cases with POLYTECH implants:

	Primary	Secondary *	Total
POLYsmoooth®	0	0	0
MESMO*sensitive*®	0	0	0
POLYtxt®	1	1	2
Microthane®	2	3	5
* previous presence of a Biocell and/or another non-Polytech implant.			

A study by Loch Wilkinson *et al*. is often quoted as reporting 15 cases of BIA-ALCL with PU implants. However, of these, 14 cases occurred with PU-implants manufactured by Silimed, and 1 with PU-implants manufactured by Surgitek.

Moreover, the authors of this study contradict themselves: they assume larger surface areas have a higher BIA-ALCL risk, they then state that polyurethane is the largest surface area, but then find much lower BIA- ALCL cases with Silimed's PU-implants compared to the 44 Allergan Biocell cases.

This study also documented 16 other BIA-ALCL cases with implants from other Manufacturers, while no cases with POLYTECH implants were found, despite the fact that our implants have been sold in a comparable time frame and comparable sales figures to Silimed's market presence.

In reality, none of the BIA-ALCL cases reported in literature concerns a POLYTECH implant.

The current risk of BIA-ALCL with POLYTECH implants is of 3 over ~1.100.000 implants sold with all our four surfaces, while the specific risk related to Microthane® is of ~1:160.000.

A recent paper on Microthane® implants even concludes that *"in fact, these coated breast implants ensure a lower rate of CC* [capsular contracture] *and, according to the current knowledge, an even lower rate of BIA-ALCL*" (Hamdi, 2019).

FACTS ABOUT BIA-ALCL

In the last 10 years, increasing concerns on a specific disease have become a prominent theme in the field of mammary implants: BIA-ALCL. BIA-ALCL is the acronym of Breast Implant Associated Anaplastic Large Cell Lymphoma: it is a rare but serious disease, and POLYTECH treats it very seriously. A scientific approach requires to take into account the following facts.

History of BIA-ALCL

BIA-ALCL has so far been classified as a rare form of non-Hodgkin's lymphoma (NHL). It typically presents itself as a late seroma containing atypical, monoclonal T-cells which are CD30+ (positive) and ALK- (negative).

The first paper reporting a BIA-ALCL case was published by Keech and Creech in 1997, followed by de Jong *et al*. in 2008.

In 2011, the Food and Drug Administration (FDA) identified a possible association between breast implants and the development of ALCL. Although ALCL may develop in any part of the body, it appeared in a higher proportion in the breast tissue of women with implants.

In 2014, a Task Force of European Ministries of Health formed, to carry out a standardized and continuous monitoring of new cases in Europe.

In March 2016, the World Health Organization (WHO) recognized and defined this emerging form of lymphoma, framing it in the latest revision of the NHL classification.

In October 2017, the Scientific Committee on Health and Emerging Risks (SCHEER) recommended to the scientific world to conduct a more in-depth assessment of the possible association between breast implants and the onset of this pathology, to allow for a solid risk assessment.

On 19 November 2018, in Amsterdam, the European Task Force chaired an international workshop called by the RIVM (the Netherlands' National Institute for Public Health and the Environment) and attended by clinical experts, Competent Authorities, Breast Implants Manufacturers and Scientific Societies. During the meeting the experts agreed that the number of BIA-ALCL cases is relatively low, to the point that no conclusions may be drawn. The same conclusion is repeated in the scientific literature on the subject.

There is a general agreementontheneedof athoroughandcoordinatedresearch strategy. Sofar, "*Although a predominance of BIA-ALCL cases has been reported in patients implanted with textured surface breast implants, to date, there is no scientific evidence to support causal correlation between the onset of this disease and the type of breast implant*" (Italian Ministry of Health).

The French decision

Following the occurrence of what it considers a high number of BIA-ALCL cases in association with textured implants, and particularly with Allergan Biocell implants, that in November 2018 the French ANSM (Agence nationale de sécurité du médicament et des produits de santé) issued the following recommendation, addressing the issue of implant surface selection:

"*In view of our recent exchanges internally at ANSM, following the meeting of experts held in February 2018, and pending the result of the next meeting of experts in February 2019, the ANSM will recommend preferably the use of breast implants with smooth shell.*"

Held on February 7th and 8th 2019 in front of a panel of experts appointed for the occasion - the CSST (Comité de santé et de sécurité) - the subsequent meeting's aim was to assess whether or not textured implants are necessary in breast augmentation and breast reconstruction, and whether or not the risk they pose in respect to BIA-ALCL is too high to leave them on the market.

Authorities, research institutes, manufacturers, patients and surgeons were invited to express their views and experiences, and provided a wealth of information on the subject of the safety, performance and benefits of textured mammary implants, as well as on BIA-ALCL. During the hearing, the importance of informed consent was emphasized, together with the institution and operation of registries that will allow the collection and comparison of data across countries.

On the basis of the figures and facts that were presented, the CSST issued a statement with its conclusions and recommendations. The CSST concluded that both in reconstruction and in aesthetic surgery, textured mammary implants provide proven benefits to a number of indications, and it further advised:

"Within the context of the recommendation by the ANSM to use preferably smooth implants and considering the reservations expressed by health professionals, the use of Allergan's Biocell texture should be prohibited. The greatest caution should be reserved for breast implants of equivalent textures and polyurethane implants. However, the committee does not recommend preventive explanation of these textured implants".

The CSST did not demand or even suggest the ban of any implant other than Allergan Biocell. If other implants or surfaces had been deemed as risk bearing as Allergan Biocell, they would have been part of the suggested ban.

The CSST further specified prominently that it does *not* recommend the preventive removal of Biocell implants.

On April 2nd, the ANSM finally made its decision, issuing the ban of several textured implants from various manufacturers, as well as our POLYtxt and Microthane implants. It is important to note that the authority does not recommend nor suggest the prophylactic removal of the concerned implants.

The decision appears to disregard the available data on BIA-ALCL, as well as the scientific and clinical data on the safety and performance specifically of our POLYtxt® and Microthane® implants which was made available to the ANSM. In general, it is also a well-known fact that textured and polyurethane surfaces allow to achieve much lower complication rates than smooth implants.

The opinion of expert surgeons and the FDA hearing of March 25, 26

The French decision also fails to consider the many experts opinions voiced by surgeons at the hearing, as well as the conclusions of the American FDA, which just a few days prior, on March 25th and 26th, 2019, held a meeting of its Advisory Committee on General and Plastic Surgery Devices.

During the FDA meeting, authorities, patients, experts, surgeons and manufacturers were invited to share their knowledge, experiences and concerns about breast implants, and BIA-ALCL was one of the main themes discussed.

The conclusions reached by the FDA Advisory Committee once again emphasized the importance of informed consent and of a transparent a comprehensive communication between manufacturers, surgeons and patients, to which all participants agreed.

All Committee members acknowledged the necessity of ongoing research - focusing on all the possible risk factors, including not only those related to possible implant characteristics, but also those related to surgical procedure techniques, genetic predisposition and immunology, as the current data does not allow to draw any conclusions.

Support for more comprehensive and comparable data collection through registries was confirmed by the authorities and manufacturers.

Experts agreed that, considering the available data on BIA-ALCL and the actual benefits that breast implants offer, any ban would be an extraordinary over-reaction.

The latest update published by the FDA confirms that there are now know and documented cases of "pure smooth implants" BIA-ALCL cases, meaning that the affected patient only ever received smooth implants. The update also emphasizes the importance of correct reporting and truthful representation of figures: of the more than 650 reports concerning BIA-ALCL cases received, 457 were confirmed after accurate review. Of the 12 casualties previously reported, 9 were finally confirmed (FDA official page on BIA-ALCL).

We have to face the fact that today, deaths by BIA-ALCL are documented. This is undoubtedly sad, and requires all those involved to treat the subject with respect and understanding for the patients. For this exact reason, fear-sparking politics, over-reactions, and the commercially-driven manipulation of the patients' emotions are not acceptable.

There are about 660 cases of confirmed BIA-ALCL known worldwide, and 17 known deaths. Of these, two patients died from stem cell transplants, one died from development of a second unrelated lymphoma, and 14 patients died from direct extension of the cancer into their chest wall, ultimately expiring from respiratory failure. Of these deaths, none received complete surgical excision at any point in the patient's clinical history, none received targeted therapy, and most were significantly delayed in diagnosis or receiving any treatment (on average 1-2 years from onset of symptoms) (American Society of Plastic Surgeons).

"*When diagnosed early, BIA-ALCL is commonly indolent and slow growing with an excellent prognosis, particularly when treated with surgery. NCCN guidelines remain the recognized standard for diagnosis and treatment and ensure that patients are managed in a timely and appropriate fashion*" (Clemens *et al*. 2019). The current increase in diagnosis is, according to experts, due to an increase in awareness, and early diagnosis leads to a very positive prognosis.

CONCLUSIONS

For patients seeking a mammoplasty, mammary implants are very important. Surgeons' everyday experiences remind us of the positive role that mammary implants have for patients in the restitution of their own image and in the building of their self-esteem, not only in reconstruction surgery. During the CSST hearing, it was acknowledged that aesthetic surgery includes many indications (asymmetry, tubular breast, hypoplasia, sagging after breast-feeding, and so on) that are truly cases of reconstruction, even though they are not taken in charge as such by most health systems.

Limiting the access to high-safety and -performance products in order to prevent a very low risk disease, which may be successfully treated if timely diagnosed, with no scientific proof of any causation relationship between such disease and the banned implants, is not the responsible approach.

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