

Position statement of IQUAM 15 July 2006

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On 15 July 2006, IQUAM issued its VIIth Position Statement, which reads as follows:

IQUAM, the International Committee for Quality Assurance, Medical Technologies and Devices in Plastic Surgery, is a professional medical and scientific organization committed to the surveillance of existing and new medical technologies, devices, and procedures in plastic surgery and is dedicated to their safe use and to the guarantee of patients' safety. IQUAM reviews and evaluates updated literature and studies, scientific data, and recommends standards of treatment for new devices or technologies. IQUAM proscribes potentially deleterious use of products, devices and technologies, or their unintended application or application for unsuitable indications.

Breast implants

The purpose of breast implant surgery is to improve the mental and physical condition of the patient. The breast implants should be chosen depending on the needs of the patient and their compatibility in the individual case.

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Silicone gel-filled breast implants

- A. Since IQUAM's former declarations, silicone gel continues to be widely used for breast implants. No better alternative material is available.
- B. Additional medical studies have not demonstrated any association between silicone-gel filled breast implants and cancer or any other disease. These studies reconfirm prior data [1–4].
- C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast-feeding, or the health of breast-fed children [5–7].
- D. Further changes in implants structure and composition need to be evaluated.

Titanium-coated breast implants

Implants made of titanium and titanium alloys are regarded as inert, and they are widely used in implantology. Nonetheless, literature reveals that metallic implants release ions, induce a cytokine cascade that resembles a pro-inflammatory cytokine, and subsequently, cellular reaction [8] and that especially titanium and titanium alloy particles and debris from fretting and wear are of concern. These particles are being transported to remote sites such as lymph nodes, liver, and spleen and even are capable of causing splenomegaly and visceral granulomatosis [9, 10]. They seem to play a critical role in the phenomenon of "aseptic loosening" of such implants, where polyethylene particles arising from joint cups may add to an unfavorable inflammatory tissue reaction [11, 12]. To our knowledge, there are and have been breast implants with their silicone envelopes coated with titanium. In regard to the experiences made with hip implants of

titanium and titanium alloys, which are per se mechanically heavily loaded, and the ongoing debate about debris and particles originating from silicone breast implants and their contribution to capsular contraction, long-term studies and tissue analysis regarding possible particulate debris including remote sites should be presented by manufacturers.

IQUAM calls for clinical and scientific research, for documentation and monitoring of breast implants and similar devices coated with titanium and recommends not using these devices before proper scientific and clinical data are available and to closely monitor patients in whom this type of breast implants were implanted.

Hydrogel-filled breast implants

The safety of the hydrogel-filled breast implants has not been established; they have been removed from the market in the U.K. [http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=738]. No new data have arisen to support the safety and efficacy of hydrogel-filled implants [13–15].

Triglyceride (soybean oil)-filled breast implants (Trilucent™)

- A. Laboratory findings and evaluation of available data [16], [Addendum I], indicate the presence of potentially hazardous components in the breakdown products of the triglyceride (soybean oil) filler [17–20].
- B. Not all of the triglyceride-filled breast implants have been explanted to date and IQUAM, therefore, emphasizes the need for immediate explantation of the remaining implants.
- C. Long term follow-up of this group of patients is recommended even after explantation.

General references: [21–40].

General recommendations for breast augmentation and reconstruction

- A. IQUAM believes it is important to advise patients of potential hazards and risks, the possible need for reoperations, and the benefits of breast augmentation or reconstructive surgery. A detailed and updated patients information and consent form must be provided and discussed with the patient before surgery.
- B. A reasonable period of time should be allotted following consultation, for the comprehension and evaluation of data before decision and performance of surgery.

- C. It is recommended to postpone breast augmentation surgery until after the age of 18 years, unless medically indicated.
- D. Patients with breast implants should have regular follow-up, preferably by the operating surgeon [41–43].
- E. No definite period of time has yet been defined for the longevity of breast implants. Routine replacement of implants is therefore not mandatory.
- F. IQUAM calls for continuous clinical and scientific research, for documentation and monitoring of breast implants and patients by means of a national and/or international registry.
- G. Advertising of breast implant procedures should be restricted to the medical aspects of the surgery, and refrain from presenting it as being risk-free.
- H. IQUAM calls for the approval of silicone-gel filled breast implants for global clinical use and unrestricted availability to all patients.

National and the International Breast Implant Registry (IBIR)

IQUAM first called for the implementation of the International Breast Implant Registry (IBIR) in its Consensus Declaration made in June 1998. The IBIR has been launched and is functioning very well. Statistics of incidence rates, risk factors, and short-term complications are now available [<http://www.ibir.org>; 44–50].

Plastic surgeons participating in the breast implant registries commit to high quality medical practice. IBIR activity should be evaluated in the framework of striving for safety and excellence.

IQUAM believes that registries of breast implants are crucial to monitor and document the safety of breast implants. IQUAM appreciates the importance of breast implant registries to ensure women's well-being and safety. National Health Authorities and National Societies of Plastic Surgery should encourage plastic surgeons to participate in national registries and/or IBIR.

IBIR enables individual plastic surgeons to submit data directly or through their national societies. It also reassures patients, surgeons, health authorities, and the general public of the commitment to safety on the part of the plastic surgery community and for the implementation of medical devices and technologies used in plastic surgery.

Public funds and other sources should be made available to further develop breast implant registries.

IQUAM endorses the IBIR and calls for registries of the national societies to link with IBIR. It is recommended that statistics gathered by national registries should be processed through IBIR.

IQUAM recommends that registration of breast implantations should be obligatory.

Tissue engineering

Tissue engineering is a promising road for future advancements in plastic surgery. Laboratory engineered constructs must consist of safe components before implantation in patients. Institutions such as C.E.N. must set strict measures.

Ultrasound-assisted lipoplasty (UAL)

- A. UAL, VASER, and external ultrasound have been used in aesthetic surgery as a substitute for or in conjunction with conventional liposuction. Immediate adverse effects have been reported and evaluated. Long-term biosafety has been questioned in light of the generation of acoustic cavitation with the consequent production of free radicals, sonoluminescence, high pressures, and thermal effects [51, 52].
- B. The use of antioxidants in clinical application of the various UAL and VASER techniques may limit associated risks [53].
- C. Further basic science research is mandatory to evaluate risks and to ensure better and safer clinical application.
- D. Safety and efficacy of external (focused) US for aesthetic use has not been established.

Injectables

Lipolysis or lipodissolve injections by Phosphatidylcholine derivatives

Phosphatidylcholine has been used for various clinical indications for many years. Phosphatidylcholine is currently being used ‘off label’ for dissolving fat in clinical aesthetic applications. Data concerning the outcome and the safety of its use have not yet been established. Further basic science and clinical trials should precede the use of this drug for aesthetic application [54–61].

Botulinum toxin A

- A. Botulinum toxin A (BTxA) has been extensively used for aesthetic purposes.
- B. BTxA in high dosages has been used in various clinical applications with minimal reported significant adverse effects.

- C. Current clinical data confirm the safety of BTxA’s for aesthetic indications when used by experienced doctors under medically acceptable conditions.
- D. Patients should be provided with detailed information, and a signed informed consent should be obtained before performing the procedure [Addendum II].

Injectable fillers

Various resorbable and non-resorbable injectable materials for soft tissue augmentation are available at present. They include biological and synthetic sources and should be classified as temporary or permanent. ‘Semipermanent’ fillers (filler containing temporary and permanent components) [62] should be regarded as permanent. The term ‘Semipermanent’ is confusing and IQUAM recommends that it should be abandoned.

Furthermore, IQUAM stresses that degradability should be discerned from resorbability.

All permanent implants are associated with risks of infection and granuloma formation, which may lead to major disfiguration. The risks depend on the nature of the implant, volume, and depth of injected material, site of injection, and multiple other factors. Permanent fillers (excluding autogenous tissue) have been reported to be associated with long-term irreversible complications and should be used with extreme caution.

IQUAM recommends reporting complications and the mandatory registration of adverse effects associated with injections of fillers to regulatory bodies to better estimate the extent of complications associated with injectable filling materials. Substantial biochemical and biophysical differences and variations in substance and purity between the commercial products exist. Not all of these have stood the test of time and several should still be considered to be experimental.

The regulation of injectables varies widely from country to country. Approval is often gained after short-term studies of only a few months. To avoid confusion in the use of materials, IQUAM recommends that users verify the validation of the CE-mark or FDA approval before clinical use.

However, appropriate guidelines are often lacking, and as their clinical use expands rapidly, there is considerable overlap in application. More choices demand greater clinical judgement and continuing clinical trials to highlight the differences, the safety, the efficacy, and the evolution of the use of these materials.

Numerous case reports describing various complications following the injection of liquid silicone raise concern regarding its use for aesthetic purposes. The main concern regarding silicone injections seems to be its migratory

capacity and the generation of early or delayed foreign body reaction [63–72]. IQAM's current position is to sustain the ban on the use of liquid silicone in aesthetic plastic surgery [<http://www.fda.gov/bbs/topics/NEWS/NEW00267.html>].

Clinical studies performed by manufacturers are not always sufficient to predict the incidence of late reactions, when a product becomes available for cosmetic purposes.

Continued long-term post-marketing surveillance by both industry and Notified Bodies is essential. Physicians should stay alert to detect late adverse events and report these to the competent authorities.

Patients and users need to be given updated information on the risks of these materials.

Supply of injectables should be limited to trained physicians.

Injections of permanent fillers in relatively high volumes, especially hydrogels, have been reported to cause severe irreversible damage, and therefore, have generated substantial concern. After reviewing the accumulated reports, IQAM recommends that permanent hydrogels should not be used due to the high incidence of severe complications [73–78].

IQAM urges governments to pass legislation plastic surgery to the public to protect patients from unduly trained physicians and nonmedical personnel injecting materials for various indications.

Based on past experience, IQAM states that CE-marks and FDA approvals are required steps in establishing the safety of medical devices, but are not necessarily sufficient. Post-market surveillance revealing new adverse information should lead to reconsideration of the approval status. Therefore, it is the IQAM's members' imperative duty to continuously monitor the short and long term outcomes to protect the safety of patients.

Objective medical and media reports contribute to the reassurance of patients. IQAM will continue to provide updated information about medical devices in general, implants in particular, injectables, and new technologies in plastic surgery.

Regensburg, Germany, 15 July 2006

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