



THE EUROPEAN AND INTERNATIONAL COMMITTEE FOR QUALITY ASSURANCE,
MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

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CONSENSUS DECLARATION OF EQUAM
26 June 2004

On 26 June 2004, EQUAM issued its Vith Consensus Declaration, which reads as follows:

EQUAM, European and international committee for quality assurance, medical technologies and devices in plastic surgery, is dedicated to the assurance of the safe use of medical devices, technologies and procedures in plastic surgery, and to the guarantee of patients' safety. After review and evaluation of current literature and scientific data, EQUAM raises concerns regarding the potentially deleterious use of products, devices and technologies, or their application for unintended or 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 on the basis of those best fitting and most suited to the individual patient.

1. Silicone Gel-filled Breast Implants.

- A. Since EQUAM's former declarations, silicone gel continues to be widely used for breast implants. No better alternative material has become available.
- B. Additional medical studies have not demonstrated any association between silicone-gel filled breast implants, cancer or any other disease. These studies re-confirm prior data.^{1,2,3,4}
- C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast feeding or the health of breast-fed children.^{5,6,7,8}

2. Titanium-coated Breast Implants.

Titanium coated breast implants (Ti-Breeze) are being introduced for clinical use. Not even short term clinical data for safety or efficacy have been provided to EQUAM. This implant has been granted a CE-mark.



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EQUAM calls for clinical and scientific research for documentation and monitoring of this device and recommends not using this device before proper clinical data are available.

3. Hydrogel-filled Breast Implants.

The safety of the hydrogel filled breast implants has not been established. Although no definite risk was identified with the use of hydrogel-filled breast implants, the MDA issued two Device Alerts in December 2000 concerning the withdrawal of these breast implants from the UK market as a precautionary measure, as not enough information was available to fully assess either of the filler materials. The MHRA (Medicines and Healthcare products Regulatory Agency), an executive agency of the British Department of Health, is "continuing to monitor the safety of these implants and at this time does not recommend that women should have them removed (unless they are experiencing problems)".⁹

Additional general references^{10,11,12}

4. Soybean Oil-filled Breast Implants (Trilucent™)

A. Laboratory findings and evaluation of available data¹³, [Addendum I], indicate the presence of potentially hazardous components in the breakdown products of soybean oil filler^{14,15,16,17}

B. Only part of the soybean oil-filled breast implants have already been explanted

C. EQUAM, therefore, emphasizes the need for immediate explantation of these implants.

D. Long term follow-up of this group of patients is recommended.

Additional general references^{18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37}

5. General Recommendations for Breast Augmentation and Reconstruction

A. EQUAM believes it is important to advise patients of potential hazards and risks, the possible need for re-operations, as well as 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 prior to surgery.

B. A reasonable period of time (at least two weeks) 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 eighteen years, unless medically indicated.

D. Patients with breast implants should have regular follow-up, preferably by the operating surgeon.^{38,39,40,41}

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. EQUAM calls for continuous clinical and scientific research for documentation and monitoring of breast implants by means of a national and/or international registry.



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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.

6. National and International Breast Implant Registries

EQUAM believes that national and international registries of breast implants are crucial to obtain information on natural behavior of implants, short- and long-term complications and risks, for post-implantation surveillance. Principles of confidentiality and the safeguarding of the privacy of both patients and surgeons must be maintained for such a registry to be successful. EQUAM upholds the necessity for national breast implant registries, which may serve as a foundation for the International Breast Implant Registry (IBIR), applying a universal form [Addendum II]. National Health Authorities and Societies of Plastic Surgery should consider how to implement and support international registries to fulfill the demands of the related standard directives and the recommendations of the European Commission.

IBIR should enable individual plastic surgeons to submit data directly and will serve to reassure patients, surgeons, health authorities and the general public of the commitment to safety on the part of the plastic surgery community in the implementation of medical devices and technologies used in plastic surgery. The next steps should be developing electronic interfaces and steering systems to maintain databases. European funds should be made available to further develop breast implant registries.

EQUAM believes that the proposed registration of breast implants should be compulsory.

Ultrasound-Assisted Lipoplasty (UAL)

A. UAL, VASER and External Ultrasound have been used in aesthetic surgery to substitute 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 cavitation with the consequent production of free radicals, sonoluminescence, high pressures and thermal effects.^{42,43}

B. The use of antioxidants in clinical application of the various UAL and VASER techniques may limit associated risks.⁴⁴

C. Further basic science research is mandatory to evaluate risks and to ensure better and safer clinical application.



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Injectables

Lipolysis or lipodissolve injections/Phosphatidylcholine.

Phosphatidylcholine has been used for various clinical indications for many years. Phosphatidylcholine is currently being used for dissolving fat in clinical aesthetic applications. Data concerning the outcome and the safety of its use have not yet been established. Clinical studies should precede the use of this drug for aesthetic application.

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 no 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 prior to performing the procedure [Addendum III].

Injectable fillers

Various resorbable and non-resorbable injectable materials for soft tissue augmentation are available at present. They include biological and synthetic sources and can be classified as temporary or permanent. Degradability should be discerned from resorbability. 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, EQUAM recommends that users verify the validation of the CE-mark or FDA approval prior to 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.

All permanent implants are associated with an increased risk of infection and foreign body reaction. The risks depend on the nature of the implant.



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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.^{45,46,47,48,49,50,51,52,53,54,55} EQUAM's current position is to sustain the ban on the use of liquid silicone in aesthetic plastic surgery.⁵⁶

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.

Based on past experience EQUAM states that CE-marks and FDA approvals are required steps in establishing the safety of medical devices, but not necessarily sufficient. Therefore, it is the EQUAM'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. EQUAM will continue to provide updated information about implants, injectables and new technologies in plastic surgery to the public.

Groningen, the Netherlands, 26 June 2004



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² United Kingdom Report of the Independent Review Group (hereinafter IRG) “Silicone Gel Breast Implants,” p25. Internet-address: www.silicone-review.gov.uk

³ European Parliament Directorate General for Research, Scientific and Technological Options Assessment (hereinafter STOA) “Health Risks Posed by Silicone Implants in General with Special Attention to Breast Implants – Final Study,” p22-23. European Parliament Resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/1998 and 771/1998) (2001/2068[INI]). Internet-address: www.europarl.eu.int

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⁵ IOM p204

⁶ IRG p24

⁷ STOA p25-26

⁸ Netherlands p34

⁹ <http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwSearchResults/9300875F7D3AF4AD80256DB2004F5E65?OPEN>

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