THE EUROPEAN COMMITTEE ON QUALITY ASSURANCE AND MEDICAL DEVICES IN PLASTIC SURGERY

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CONSENSUS DECLARATION OF EQUAM
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On 6 July 2002, EQUAM issued its Vth Consensus Declaration, which reads as follows:

EQUAM, the European Committee on Quality Assurance and Medical 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 technology, or their application for unintended or unsuitable indications.

Breast Implants

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

A. Recent laboratory findings and evaluation of available data [1], [Addendum I], indicate the presence of potentially hazardous components in the breakdown products of soybean oil filler [2], [3], [4], [5].
B. EQUAM, therefore, emphasizes the need for immediate explantation of these implants.

2. Silicone Gel-filled Breast Implants

A. Since EQUAM's former declarations, silicone continues to be widely used. No better alternative material has become available.
B. Additional medical studies have not demonstrated any association between silicone-gel filled breast implants and traditional auto-immune or connective tissue diseases, cancer or any other malignant disease. These studies re-affirm prior data [6], [7], [8], [9].
C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast feeding or the health of breast-fed children [10], [11], [12], [13].
D. EQUAM believes it is important to advise patients of the hazards and risks as well as the benefits of breast augmentation or reconstructive surgery and has prepared a Patients Information

and Consent Form to be used in discussion with the patient. A reasonable period of time should be allowed between consultation and surgery. It is recommended to postpone the insertion of implants until after the age of eighteen years, unless medically indicated.

E. Patients with breast implants should have regular follow-up [14], [15], [16], [17].

F. No routine replacement of implants is mandatory.

G. EQUAM calls for continuous clinical and scientific research for documentation and monitoring of breast implants.

3. National and International Breast Implant Registries

EQUAM believes that national and international registries of breast implants are crucial to obtain information on short- and long-term complications and risks, and 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].

The IBIR 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.

Ultrasound-Assisted Lipoplasty (UAL)

A. Various UAL techniques 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 [18],[19].

B. The use of antioxidants in clinical application of the various UAL techniques may limit associated risks[20].

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

Botulinum Toxin A

A. Botulinum Toxin A (BTxA) is now widely used for aesthetic purposes.

B. BTxA in high dosages has been used in various clinical applications with no reported significant adverse effects.
C. EQUAM welcomes updated clinical data in confirming BTxA's safety and calls for the adoption of the FDA's approval for its use in appropriate aesthetic indications 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].

Injectables

Various resorbable and non-resorbable injectable materials for soft tissue augmentation are available at present. Substantial biochemical and biophysical differences and variations in 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.

Due to disturbing reports of severe soft tissue atrophy following the injection of "METREX" (manufactured by Derma Pharma, Lucerne, Switzerland), EQUAM issues a hazard notice for further use of this product.

Numerous case reports describing various complications following the injection of liquid silicone raise concern regarding its continued 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 [21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31]. EQUAM joins the FDA's current position in its ban of the use of liquid silicone in aesthetic plastic surgery[32]

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 notifying bodies is essential.
Patients and users need to be given updated information on the risks of these materials.
Supply of injectables should be limited to trained physicians.
Users of the various injectables are required to report adverse events to the competent authorities and manufacturers.

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, 6 July 2002

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[2] MDA HN 2000(05) June 2000 Trilucent™ Breast Implants: Recommendation to Remove. Manufacturer/supplier Lipomatrix Inc. / AEI Inc. (formerly Collagen Aesthetics International Inc.) Internet-address: http://www.medical-devices.gov.uk

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[10] IOM p204

[11] IRG p24

[12] STOA p25-26

[13] Netherlands p34

[14] IOM p215

[15] IRG p25

[16] STOA p23

[17] Netherlands p11

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