EUROPEAN COMMITTEE ON QUALITY ASSURANCE AND MEDICAL DEVICES IN PLASTIC SURGERY

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CONSENSUS DECLARATION ON BREAST IMPLANTS
23 June 2000

EQUAM, the European Committee on Quality Assurance and Medical Devices in Plastic Surgery, raises concerns regarding the potentially deleterious use of products, devices and technology, or their application in unsuitable indications. EQUAM aims to ensure that both medical devices and technologies used in plastic surgery are safe, and to guarantee the safety of patients.

On 23 June 2000, EQUAM issued its consensus declaration, which read as follows:

1) Since EQUAM's 1998 declaration, silicone has continued to be a widely used and essential material in every day life. No better alternative material has become available. In all fields of medicine and surgery, implants and medical devices made of silicone remain essential not only for aesthetics, but also for reconstructive procedures and to support survival.

2) Additional medical studies have not demonstrated any association between silicone-gel filled breast implants and traditional auto-immune or connective tissue diseases, cancer nor any other malignant disease. These studies re-affirm prior data. [1], [2], [3], [4]

3) EQUAM states that there are new conclusive scientific, clinical, immunological and epidemiological data indicating that silicone-gel filled breast implants do not cause any traditional auto-immune or connective tissue diseases.[5], [6], [7], [8], [9]

4) EQUAM continues to believe that there is no scientific evidence that silicone allergy, silicone intoxication, atypical disease or a "new silicone disease" exist. Normal foreign body reaction occurs with every type of implant but this is not immune disease. [10], [11], [12], [13], [14]

5) Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast feeding or the health of breastfed children. [15], [16], [17], [18]

6) Patients with breast implants should have regular follow-up and, if indicated, appropriate imaging of the breasts.[19], [20], [21], [22]

7) Laboratory tests to detect silicone are of no clinical value. No specific antibodies against silicone have been detected. [23], [24], [25], [26]

8) There is no valid scientific evidence to associate silicone or silicone-gel filled breast implants with neurological disease or symptoms. [27], [28], [29], [30]

9) EQUAM agrees with the IOM that breast implants can produce severe local complications by themselves, which may result in medical and surgical interventions with their associated risks. [31]

10) EQUAM believes it is extremely important to advise the 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.

11) EQUAM believes there is a continuing need for a functioning, harmonised, specific EU-standard for breast implants. EQUAM endorses the Guidelines for Conformity Assessment of Breast Implants. [32]

12) EQUAM calls for continuous clinical and basic science research to provide more accurate information on rupture rates of breast implants and better definition of the longevity of all silicone gel, saline, and other filler materials of breast implants.

13) EQUAM believes that a European and world-wide registry of patients is crucial for identifying information on short-term complications such as capsular contracture or rupture, and to provide a database for long-term research on breast implants. Principles of confidentiality and the safeguarding of the privacy of patients must be maintained for such a registry to be successful.

14) Objective media reports contribute to the reassurance of patients. EQUAM will continue to provide updated information about implants and new technologies in plastic surgery to the media.

15) After evaluation of current data, EQUAM joins the British Medical Devices Agency in their recommendation of June 6, 2000 for removal of the soybean oil-filled (Trilucent) implants.

16) Based on current knowledge, EQUAM confirms the safe use of silicone gel and saline-filled breast implants.

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CONSENSUS DECLARATION ON ADVANCED TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY
23 June 2000

EQUAM, the European Committee on Quality Assurance and Medical Devices in Plastic Surgery, raises concerns regarding the potentially deleterious use of products, devices and technology, or their application in unsuitable indications. EQUAM aims to ensure that medical devices and technologies used in plastic surgery are safe, and to guarantee the safety of patients.

On 23 June 2000, EQUAM issued its consensus declaration, which read as follows:

Ultrasound-Assisted Lipoplasty (UAL)

1.The UAL technique has been applied as an additional tool to conventional liposuction. Immediate effects have been reported and evaluated. Long-term bio-safety has been questioned in light of the possible generation of cavitation with the consequent production of free radicals, sonoluminescence, high pressures and thermal effects.

2. Further basic science research is mandatory to evaluate risks and for better and safer clinical application.

Botulinum Toxin A

1. Botulinum Toxin A has been widely applied for aesthetic use either to replace or in combination with surgery.
2. EQUAM accepts updated clinical data in confirming Botulinum Toxin A's safety for application in aesthetic plastic surgery.

Herzliya, Israel, 23 June 2000

References:

[1] Bondurant S, Ernster V, Herdman R (eds). Safety of Silicone Breast Implants, Report of the Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine (hereinafter IOM). National Academy Press, Washington, D.C., June 22, 1999, p187. Internet address: www4.nationalacademies.org/news.nsf
[2] United Kingdom Report of the Independent Review Group (hereinafter IRG) "Silicone Gel Breast Implants," p25.
[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.
[4] Health Council of the Netherlands (hereinafter Netherlands) "Gezondheidsrisico's van siliconen–borstimplantaten – Health Risks of Silicone Breast Implants" English Executive Summary, p11.
[5] IOM p175
[6] IRG p22
[7] STOA p24
[8] Netherlands p10-11
[9] U.S. District Court Northern District of Alabama Rule 706 National Science Panel (hereinafter NSP) Report "Silicone Breast Implants in Relation to Connective Tissue Disease and Immunologic Dysfunction" p6-7.
[10] IOM p179-180
[11] IRG p23
[12] STOA p25
[13] Netherlands p10-11
[14] NSP p7
[15] IOM p204
[16] IRG p24
[17] STOA p25-26
[18] Netherlands p34
[19] IOM p215
[20] IRG p25
[21] STOA p23
[22] Netherlands p11
[23] IOM p166
[24] IRG p19
[25] Netherlands p24-26
[26] NSP (II)p16-24
[27] IOM p191-192
[28] IRG p23
[29] STOA p23
[30] Netherlands p32-33
[31] IOM p2-3
[32] Guidelines for Conformity Assessment of Breast Implants According to Directive 93/42/EEC Relating to Medical Devices.