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Varia

Consensus Declaration of EQUAM 6 July 2002

The European Committee on Quality Assurance and Medical Devices in Plastic Surgery

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, indicate the presence of potentially hazardous components in the breakdown products of soybean oil filler.
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.
C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast feeding or the health of breast-fed children.
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.
F. No routine replacement of implants is mandatory.
G. EQUAM calls for continuous clinical and scientifc 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 confdentiality 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.

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 implementationof medical devices and technologies used in plastic surgery.

Przedstawiam fragment najnowszego dokumentu European Committee on Quality Assurance and Medical Devices in Plastic Surgery. Może on być przedmiotem zainteresowania środowiska onkologicznego, dotyczy bowiem wszczepów piersiowych (endoprotez), używanych m.in. do rekonstrukcji.

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