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**9<sup>th</sup> POSITION STATEMENT OF IQUAM**  
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IQUAM issues its 9th Position Statement, which is for use and reference by practicing physicians worldwide, and by international health care and governmental organizations:

IQUAM, the International Committee for Quality Assurance and Medical Devices in Plastic Surgery, is a professional medical and scientific organization committed to the surveillance of existing and new technologies and devices in Plastic Surgery. IQUAM serves as the clearinghouse committee of IPRAS, the International Confederation for Plastic, Reconstructive and Aesthetic Surgery. IQUAM is dedicated to the safe use of medical devices, technologies and procedures in plastic surgery, 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 Augmentation and Reconstruction**

The purpose of breast augmentation and reconstruction is to improve the psychological and physical condition of the patient. The breast augmentation method should be chosen depending on the needs of the patient and the compatibility in the individual case.<sup>1-5</sup>

#### **1. Silicone Breast Implants.**

A. Since IQUAM's previous declarations, silicone implants filled with either silicone gel or saline, textured by various methods or smooth surfaced, or covered by polyurethane, continue to be widely used internationally for breast implantation, with the implant types varying by geographic region.



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B. Additional medical studies have not demonstrated any association between silicone-gel filled breast implants and carcinoma or any metabolic, immune or allergic disorder. These studies re-affirm prior data.<sup>6-11</sup>

Recent case reports about incidents of lymphoma formation in capsular tissue need further work-up

C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast-feeding or the health of breast-fed children, based on current data.<sup>12-15</sup>

#### D. Acellular Dermal Matrices

In breast surgery there is accumulated evidence that some ADMs are safe to use in the breast and in association with breast implants and tissue expanders. Those ADM's that have literature based safety and efficacy profiles should be used preferably

1. When implanted, Acellular Dermal Matrices (ADM) can undergo one of the following:

- Regeneration/ integration
- Resorption
- Encapsulation

Only those products that have been demonstrated to regenerate and integrate with the host tissue are to be recommended for implantation.

2. ADM's must be stored, handled and prepared according to the manufacturer's recommendations. They also require appropriate surgical technique by adequately trained surgeons.<sup>16-18</sup>

## 2. Autologous breast reconstruction

Surgical methods for breast reconstruction with autologous tissue such as microsurgical tissue transfer, pedicled flaps and local flap techniques undergo constant re-evaluation and are well established for individual indications and conditions. They have been employed in combination with silicone breast implants without specific inherent complications reported.<sup>19-23</sup>

## 3. Autologous fat grafting and augmentation techniques

Fat grafting for soft tissue defects has been performed for over 40 years with low complication rates. Ongoing studies show promising results of fat grafting procedures for breast reconstruction and augmentation. There is evidence that the volume of the fat grafts and its take can be increased by the preoperative and



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postoperative use of an external vacuum device. No negative effects for mammography have been found. More studies are encouraged to further evaluate the efficacy and optimal duration of vacuum application.<sup>24-27</sup>

#### **4. Other Alternatives for Breast Augmentation**

New materials and methods, such as exogenous injectable materials, including potentially fully resorbable products such as stabilized hyaluronic acid are under review.<sup>28</sup>

#### **5. Clinical Recommendations for Breast Augmentation and Reconstruction**

A. IQUAM 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 should be allotted following consultation as a cool-off period before decision and performance of surgery.

C. It is recommended to postpone breast augmentation surgery for other than reconstructive indications until after the age of eighteen. Such procedures in teenagers require in depth evaluation of motivation and maturity before considering surgery, even in medically indicated cases.

D. Patients with breast implants should be encouraged to have regular and long term follow-up, preferably by the operating surgeon.<sup>29,30</sup>

E. No definite period of time has yet been defined for the longevity of breast implants, and routine replacement is not recommended. The indications for replacement should be based on specific patient indications.

F. IQUAM calls for continuous clinical and scientific research, for documentation and monitoring of breast implants and patients and international coordination of national registries.

G. Advertising of breast implant procedures should be restricted to the medical aspects of the surgery, and presented in a professional dignified way and without exaggerated claims.

H. IQUAM calls for the approval of medical grade silicone gel filled breast implants according to national and international standards and certifications for clinical use and unrestricted availability to all patients.



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## **Liposuction**

The proper processing of multiple-use cannulas is especially important considering the recent reports of mycobacterial infections related to liposuction and fat injections.<sup>31-41</sup> Cannulas used for the removal and the placement of fatty tissue can be multiple-use or single-use.

The reprocessing of multiple-use cannulas is a labor-intensive process, which requires meticulous attention to detail particularly with regard to the non-visible surfaces. Autoclaving should always be performed. Thorough cleaning of all exposed and hidden surfaces followed by removal of all cleaning agents is essential before autoclaving. The autoclave must be used at appropriate settings to eliminate bacteria and minimize mycobacterium, prions and biofilms.

Exposure to some cleaning agents, especially in combination with high temperatures, may cause degradation of the cannula. Instruments showing corrosion or damage should not be used.

If suitable reprocessing of multiple-use cannulas is not available, single-use cannulas should be considered. The manufacturer of such single-use cannulas must process and package the cannulas according to good manufacturing practices and in a fashion approved by the FDA or a country or region's regulatory agencies. This process should assure sterility and appropriate packaging, which prevents accidental contamination.

## **Tissue Engineering and Wound Healing**

Tissue engineering holds the promise of generating tissues de novo. Adipose tissue is an ideal soft tissue surrogate to redefine body contour defects due to its intrinsic plastic characteristics.

Regenerative medicine 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., are setting strict standards<sup>42-45</sup>



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## 1. Stem Cell Therapy

One of the most exciting frontiers in medicine today is the use of stem cells. Unlike the controversial evaluation of embryonic stem cells, adult stem cells deriving from adipose tissue are easily available without ethical controversy.

Respecting the guidelines that

- the injections are performed in the same operative session as the liposuction procedure to remove the fat
- the stem cells have been only minimally manipulated and
- the therapeutic use of autologous stem cells is not submitted to drug therapy regulations.

Reinjection of autologous stem cells in a separate session therefore is not recommended.

For over a decade now it has been shown that successful autologous fat grafting is highly dependent on the techniques used for extracting (liposuction at low negative pressure), processing (centrifugation and decanting of the extracted fat) and reinjection to result in a high concentration of adult stem cells, producing long lasting results and even therapeutic effects in injured tissues.

Indications of stem cell containing adipose tissue transfer under the above conditions include augmentation of the subcutaneous layer, e.g. for defects after liposuction complications and other acquired tissue defects e.g. burns

Under investigation to date are treatments of radiotherapy injuries and breast reconstruction after cancer. Stimulated by encouraging experience with fat grafting, numerous basic laboratory and animal model studies are underway in many parts of the world.<sup>46-51</sup>

## 2. Growth Factors

An increasing number of growth factors are becoming commercially available for a wider range of indications, either as a therapeutic agent or as an element of tissue engineered constructs. IQUAM is concerned that application of growth factors may occur before potential adverse effects (uncontrolled cell divisions, malignancies) have been diligently, adequately studied. Notified bodies issuing CE-mark certifications should be aware of this and grant only temporary CE-marks, while awaiting longer term studies.<sup>52, 53</sup>



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### **3. Shock Wave Therapy**

Recent studies suggest that Extra Corporal Shock Wave Therapy originally developed for resolution of kidney stones, is useful in the treatment of chronic wounds, burns and tendon adhesion. More studies are needed to evaluate the optimal techniques for application and duration. <sup>54-56</sup>

### **Injectable Therapies**

#### **Lipolysis or Lipodissolve Injections by Phosphatidylcholine Derivatives.**

Phosphatidylcholine has been used for prevention and treatment of fat embolism for many years, but is currently being used ‘off label’ for dissolving fat in aesthetic applications. Data concerning the efficacy, outcome and the safety of its use for aesthetic indications in then subcutaneous tissue have not yet been established. Further basic science and clinical trials, such as PMA trials underway are needed. <sup>57-60</sup>

#### **1. Botulinum Toxin A**

Botulinum Toxin A (BTxA) has been used extensively for aesthetic purposes. BTxA in high dosages has been used in various therapeutic clinical applications with minimal reported significant adverse effects. Current clinical data confirm the safety of BTxA’s for aesthetic indications when used by experienced doctors under sterile office environment. Patients should be provided with detailed information, and a signed informed consent should be obtained prior to performing the procedure [Addendum III].

#### **2. Injectable fillers**

Today more than 35% of the procedures performed by plastic surgeons are no longer purely surgical. The use of resorbable substances is preferable to the use of non-resorbable fillers, as recommended by many national health authorities or



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

Permanent fillers (excluding autogenous tissue) can give a definitive correction, but have been reported to be associated with long-term irreversible complications and should be used with extreme caution. Risks depend on the nature of the implant, volume, depth and site of the injection especially in permanent substances, but also in resorbable products.

The patient's history and the long-term follow up are important for documenting allergic or late reactions. IQUAM recommends reporting complications of fillers to regulatory bodies and mandatory registration of adverse effects associated with injection of fillers to better estimate the extent of complications.<sup>61-64</sup>

### **3. Collagen Fillers**

Collagen derived soft tissue fillers from bovine origin that are in use for soft tissue augmentation lately have reduced clinical impact and have few chemical or manufacturing changes. Most of the available products can be employed only after a negative allergy skin testing at least 6 weeks before injection. This is not the case for a porcine derived product where the local complication rate like infection, granuloma, nodule formation, visibility or allergies have not been reported so far.<sup>65-67</sup>

### **4. Hyaluronic Acid Fillers**

Commercially available HA's have a wide variety of properties which have an impact on their use and clinical outcomes. Combining objective factors that influence filler chemistry with clinical experience will improve patient care, make optimal results more likely, and should decrease complications.

Regulation of these injectables varies widely from country to country and approval is often gained after short term studies of one year or less. To avoid confusion in the use of materials, IQUAM recommends that users verify the validation of the CE-mark or FDA approval prior to clinical use.<sup>68-74</sup>

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



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updated information on the risks of these materials. Supply of injectables should be limited to trained physicians.<sup>75-79</sup>

## **5. Cross Linked Polyacrylamide Hydrogel**

Permanent fillers based on acrylamides have been in clinical use for more than 15 years. The current European manufacturer has attained CE certification, with remaining monomer content below 2 ppm, which is considered a non-carcinogenic level; and claims superior production standards compared with earlier acrylamide products, especially from non-E.U. countries. Used strictly subcutaneously and in small volumes by experienced surgeons this hydrogel has shown efficacy, and comparable complication rates as resorbable fillers in a European multicenter 8-year follow up study. Removal of the gel is possible, but will require a surgical setting and an experienced surgeon.<sup>80-88</sup>

## **6. PolyMethylMethAcrylate /Collagen Injectable Filler**

In 2008 the FDA issued the first approval for a permanent dermal filler for nasolabial folds. The approved product has undergone multiple additional cleaning processes (Suneva Medical). IQUAM emphasizes that this approval does not include substances with similar or “comparable” components from other manufacturers. Indications, contraindications need to be regarded and injection by experienced physicians are essential.<sup>89</sup>

## **7. Gold Threads**

The implantation of thin gold threads in flaccid facial cutaneous areas has been developed by Caux 50 years ago. Histologically the absence of foreign body reaction with no macrophage cells or allergic reactions used as eyelid correction for facial palsy or odontologic treatments is proven. Only limited creation of reticulin fibers can be observed.

However plication, rupture, palpability and migration of the threads due to the mobility of the face are frequent. Efficacy has not been proven and therefore these devices cannot be considered as standard for facial rejuvenation<sup>90</sup>



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## **General recommendations regarding injectable therapies**

IQUAM urges governments to pass legislation to prohibit the use of non-certified products and to protect patients from untrained physicians and non-medical personnel injecting or implanting materials for various indications. Based on past experience IQUAM 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. IQUAM will 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. IQUAM will continue to provide updated information about medical devices in general, implants in particular, injectables and new technologies.



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## Addendum

### **BOTULINUM TOXIN TYPE A INFORMED CONSENT \*** *(Botox Cosmetic)*

Botox is made from Botulinum Toxin Type A, a protein produced by the bacterium *Clostridium botulinum*. For the purpose of improving the appearance of wrinkles, small doses of the toxin are injected into the affected muscles blocking the release of a chemical that would otherwise signal the muscle to contract. The toxin thus paralyzes or weakens the injected muscle. The treatment usually begins to work within 24 to 48 hours and can last up to four months. The Food and Drug Administration (FDA) approved the cosmetic use of Botulinum Toxin Type A for the temporary relief of moderate to severe frown lines between the brow and recommends that the procedure be performed no more frequently than once every three months.

It is not known whether Botulinum A Toxin can cause fetal harm when administered to pregnant women or can affect reproductive capabilities. It is also not known if Botulinum A Toxin is excreted in human milk. For these reasons, Botulinum A Toxin should not be used on pregnant or lactating women.

I authorize and direct \_\_\_\_\_, M.D., with associates or assistants of his or her choice, to perform the following procedure of Botulinum A Toxin injection(s) on \_\_\_\_\_ for the treatment of \_\_\_\_\_ (Patient Name) \_\_\_\_\_ (e.g. brow, forehead, crow's feet, etc.)

\_\_\_\_\_ The details of the procedure have been explained to me in terms I understand.

\_\_\_\_\_ Alternative methods and their benefits and disadvantages have been explained to me.

\_\_\_\_\_ I understand that the FDA has only approved the cosmetic use of Botulinum A Toxin for frown lines between the brow. Any other cosmetic use is considered off label.

\_\_\_\_\_ I understand and accept the most likely risks and complications of Botulinum A Toxin injection(s) include but are not limited to:

- *disorientation, double vision, or past pointing*
- *temporary asymmetrical appearance*
- *abnormal or lack of facial expression*
- *inability to smile when injected in the lower face*
- *facial pain*
- *product ineffectiveness*
- *paralysis of a nearby muscle that could interfere with opening the eye(s)*
- *local numbness*
- *headache, nausea, or flu-like symptoms*
- *swallowing, speech, or respiratory disorders*
- *swelling, bruising, or redness at injection site*

\_\_\_\_\_ I understand and accept that the long-term effects of repeated use of Botox Cosmetic are as yet unknown. Possible risks and complications that have been identified include but are not limited to:

- *muscle atrophy*
- *nerve irritability*
- *production of antibodies with unknown effect to general health*

- \_\_\_\_\_ I understand and accept the less common complications, including the remote risk of death or serious disability that exists with this procedure.
- \_\_\_\_\_ I am aware that smoking during the pre- and postoperative periods could increase chances of complications.
- \_\_\_\_\_ I have informed the doctor of all my known allergies.
- \_\_\_\_\_ I have informed the doctor of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies, and any others.
- \_\_\_\_\_ I have been advised whether I should take any or all of these medications on the days surrounding the procedure.
- \_\_\_\_\_ I am aware and accept that no guarantees about the results of the procedure have been made or implied.
- \_\_\_\_\_ I have been informed of what to expect post-treatment, including but not limited to: estimated recovery time, anticipated activity level, and the necessity of additional procedures if I wish to maintain the appearance this procedure provides me.
- \_\_\_\_\_ I am not currently pregnant or nursing, and I understand that should I become pregnant while using this drug there are potential risks, including fetal malformation.
- \_\_\_\_\_ If pre- and postoperative photos and/or videos are taken of the treatment for record purposes, I understand that these photos will be the property of the attending physician.
- \_\_\_\_\_ I understand that these photos may only be used for scientific or reco *(Over, please)*
- \_\_\_\_\_ The doctor has answered all of my questions regarding this procedure.
- \_\_\_\_\_ I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

## Patient Consent

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

\_\_\_\_\_  
Patient Signature/Date

\_\_\_\_\_  
Witness Signature/Date

\_\_\_\_\_  
Print Patient Name

\_\_\_\_\_  
Print Witness Name



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## Physician Certification

I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives to the proposed procedure to the patient. I have answered all questions fully, and I believe that the patient fully understands what I have explained.

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date

Copy was given to patient: \_\_\_\_\_  
Date Initials

Original was placed in chart: \_\_\_\_\_  
Date Initials

\* Provided by The Doctors Company, USA.



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