ISAPS® ENDORSED SAFETY STATEMENT

STATEMENT ON PATIENT SAFETY DURING GLUTEAL FAT GRAFTING ENDORSED BY THE INTERNATIONAL SOCIETY FOR AESTHETIC PLASTIC SURGERY (ISAPS), AMERICAN SOCIETY OF PLASTIC SURGEONS (ASPS), THE PLASTIC SURGERY FOUNDATION (PSF), THE AESTHETIC SOCIETY, AND THE AESTHETIC SURGERY EDUCATION AND RESEARCH FOUNDATION (ASERF)

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BACKGROUND

Gluteal fat grafting, commonly known as "Brazilian Butt Lift" or BBL, has seen an increase in popularity in recent years. It is well-recognized that this procedure carries significant risk compared to other elective aesthetic surgical procedures[1, 2] and as a result, its increased popularity has resulted in deeply concerning levels of patient harm and mortality. While statistics are difficult to obtain, there is no question that gluteal fat grafting patients are experiencing abnormally high levels of complications and that fatalities from fat embolisms[3, 4] are occurring with disturbing frequency.

In 2018 and 2019, two multi-society safety advisories raised awareness of the risks associated with gluteal fat grafting and called on our members and the public to approach the procedure with extreme caution[5, 6]. Following those advisories in the United States, the Florida Board of Medicine mandated new standards of care for gluteal fat grafting that sought to reduce patient harm by requiring that fat be injected only into the subcutaneous space, above the gluteal fascia.

Recently, the State of Florida instituted additional emergency rules limiting gluteal fat grafting procedures to three per day and requiring the use of ultrasound to monitor the location of the tip of the cannula while fat is injected. Our Societies support these patient safety measures and believe that they are likely to save lives and reduce morbidity. We hope that further scientific study will demonstrate that the measures adopted in Florida achieved their intended purpose, but we stand ready to do more and reconsider approaches if they do not.

Our Societies acknowledge and commend the significant actions taken to date in the United States and internationally to improve the safety profile of this procedure.

Positions on Gluteal Fat Grafting

Given the international scope of this problem, the Executive Committees of our Societies have adopted several positions with respect to gluteal fat grafting as critical to the overarching pursuit of gluteal fat grafting safety.

1. **Training, Credentialing and Privileging Standards.**
   Gluteal fat grafting, like any plastic surgery procedure, when performed in an office-based setting, should only be performed by surgeons who have privileges to perform that surgical procedure in a country- or state-approved or licensed ambulatory surgery center or hospital.

2. **Real-Time Ultrasound-Assisted Gluteal Fat Grafting.**
   Public policy interventions targeting surgical gluteal fat grafting techniques are appropriate given the patient safety emergency that currently exists. As an adjunct to the skill and judgment of a qualified surgeon, real-time imaging during gluteal injection is a common-sense step toward ensuring that surgeons are staying above the fascia of the gluteal muscles[7, 8]. Our Societies are committed to ensuring members are appropriately proficient in ultrasound technique and will work to develop best practice guidance and educational opportunities for members related to the safe provision of gluteal fat grafting. We support mandates by official governing regulatory bodies to require the use of ultrasound to ensure delivery of the fat graft in a safe anatomic plane.

3. **Pre- and Postoperative Care and Oversight.**
   Surgeons should be actively engaged with their patients before surgery and establish a doctor-patient relationship. Surgeons should manage both standard post-operative care and be available to manage all complications for their patients. This should be the case whether the patient is local or has traveled from another country or state to undergo the procedure. Surgeons who treat patients at a distance need comprehensive pre- and postoperative clinical care protocols and should be available to directly provide care or participate in managing post-op complications.

4. **Ethical Facility Operations.**
   Business operations of some facilities performing gluteal fat grafting represent an area of serious concern. Untrained or under-trained surgeons or non-surgeon operative assistants should not perform critical portions of a gluteal fat grafting procedure, including both injection of fat as well as the lipo harvest. Member surgeons of our Societies should not practice in facilities that engage in this conduct and should follow the specialty's position statement on concurrent surgery[9]. Business models that endanger patients in the pursuit of profits should not be tolerated, and our Societies support those practice models that truly prioritize patient safety and quality outcomes. Concerns over a high number of cases per surgeon/per day have been raised by certain states relative to safety.

FUTURE DIRECTIONS

There is a necessity to address this clear patient safety imperative for our specialty. Gluteal fat grafting deaths are occurring across medical settings, from poorly regulated strip mall clinics to accredited surgical centers.

Our Societies will proactively investigate the safety and efficacy of various clinical approaches and will educate and train members on those approaches that are most likely to improve the safety of our patients. We, along with key stakeholders, will sponsor additional research and/or collection of real-world evidence to validate clinical approaches scientifically. At the same

time, we will endeavor to shape public policy and support state, federal and country-specific regulations until the safety outcomes of gluteal fat grafting are comparable to other elective aesthetic surgical procedures. We realize the importance of real-time data in these efforts and strongly encourage surgeons to enter their data in the GRAFT registry.

Given the international nature of ISAPS and the differing jurisdictions in which its members work, ISAPS will continue to review the international consensus and periodically update its position in this area as new information emerges.

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