



## Customer Service

Phone: 678-942-3794

Fax: 1-844-248-7528

LipogemsCS@gmlx.us.com

**Overview:** Lipogems International is an Italian-based company which operates globally in the biotechnology and regenerative medicine sectors. The LIPOGEMS® team prides itself on the production of the next generation adipose tissue technology through a mechanical, “enzyme-free” approach to achieve a non-expanded, and minimally manipulated product. The LIPOGEMS® device is designed for the processing and resizing of autologous adipose tissue for a convenient point-of-care procedure, which can be performed in the clinic or surgery center. The FDA-cleared LIPOGEMS® kits are disposable, intended for single-use, and operate in a closed-loop system for optimal efficiency and sterility. The mild mechanical forces exerted on the adipose tissue by the LIPOGEMS® device gently washes the tissue in order to maintain the stromal vascular niches in adipose tissue aggregates. The use of adipose tissue has been well documented in literature for regenerative medicine and other healing applications. LIPOGEMS® technology has optimized the use of adipose tissue by creating a device to micro-fracture and rid the tissue of inflammatory debris that can be harmful for a patient’s recovery. LIPOGEMS® promotes the body’s natural regenerative process for the healing of tissues for a variety of autologous applications, including, but not limited to, orthopaedic surgery, plastic and reconstructive surgery, and general surgery.

**Regulatory:** Lipogems is FDA-cleared as a 510(k) device. The device is intended for the closed-loop processing of adipose tissue. FDA's regulations set forth the criteria that must be met for an HCT/P to be regulated solely under section 361 of the PHS Act under 21 CFR 1271. These criteria are that the HCT/P must:

- Be minimally manipulated; be intended for homologous use only, as reflected in the labeling, advertising, or other indications of the manufacturer's objective intent;
- Not be combined with a drug or device, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of the water, crystalloids, or sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- Not have a systemic effect and not be dependent on the metabolic activity of living cells for its primary function except if for autologous use, allogeneic use in a first-degree or second-degree blood relative, or reproductive use.

FDA regulations further define “minimal manipulation” for structural tissue as “processing that **does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.**”

### Lipogems advantages for hospital/clinic use

- No additional equipment required (centrifuge, hood, etc.)
  - Lipogems kit is single-use and disposable
  - Only requires sterile saline to remove the oily and bloody residues from the adipose tissue
- Maintains the native structural scaffold of adipose tissue for reconstructive purposes
- Efficient and convenient for clinic or operating room use