



Guidance on Verbiage

Why?

- Lipogems is an FDA-cleared medical device. Therefore, we are able to promote the on-label indications for the device. Lipogems is not pharmaceutical product or a drug. Lipogems is a medical device used to harvest, concentrate, and transfer autologous adipose tissue. Adipose tissue processed by the Lipogems device is “minimally manipulated”, per FDA’s criteria for Human Cell and Tissue products (HCT/P).

What can you say?

- You can discuss what fat is:
 - Fat is a structural tissue and performs a structural function in the recipient, for example, to physically support or serve as a barrier or conduit, or connect, cover, or cushion.
 - According to the FDA’s guidance document “Adipose Tissue: Regulatory Considerations”, HCT/Ps include adipose tissue and cells obtained from adipose tissue. Adipose tissue is typically defined as a connective tissue that stores energy in the form of lipids, insulates the body, and provides cushioning and support for subcutaneous tissues and internal organs. It is composed of clusters of cells (adipocytes) surrounded by a reticular fiber network and interspersed small blood vessels, divided into lobes and lobules by connective tissue septa. Additionally, adipose tissue contains other cells, including preadipocytes, fibroblasts, vascular endothelial cells, and a variety of immune cells. Because connective tissue provides structure and support to the body, FDA considers connective tissue, including adipose tissue, to be a structural tissue.
 - Additionally, for purposes of applying the regulatory framework, Lipogems considers adipose tissue to be a structural tissue, with characteristics for reconstruction, repair, or replacement that relate to its utility to cushion and support the other tissues.
 - Adipose tissue has many natural reparative characteristics that help to promote a healing environment throughout the body and has been widely studied in the literature and is known to have an innate healing potential. As an example, the use of fat in medicine was documented during World War I to aid in the healing of soldiers’ battle wounds. Since then, a large body of research has demonstrated a variety of promising applications for adipose tissue in healing and regenerating damaged tissue.
 - Practical & Scientific benefits of adipose tissue
 - Research has shown that regardless of a person’s age, their fat maintains certain reparative properties unlike other tissues such as bone marrow, which may lose healing capacity with age
 - Autologous source, abundant in most patients, and minimally invasive to harvest
 - Plentiful volume, which allows for treatment of multiple sites, unlike other therapies such as bone marrow (BMAC) and amniotic tissue
 - It has been reported in studies that adipose tissue may contain 100-500x more regenerative cells than an equivalent volume of bone marrow aspirate
 - High concentration of micro-vessels, which harbor specialized healing cells: perivascular cells also called pericytes
 - Type of cell that is wrapped around small blood vessels within adipose tissue
 - Known to react to a site of injury and promote a reparative environment
 - Natural repair mechanism by communicating with local tissues to aid in healing
- You can discuss what the device does:
 - Lipogems, is a micro-fragmented tissue that is intended for the repair, replacement, cushion, and support of damaged or injured tissues.



- The LIPOGEMS® device gently washes inflammatory impurities from the adipose tissue (blood and oil) using saline and resizes the adipose tissue to create an optimal size to inject the LIPOGEMS precisely into desired tissue locations by the physician to support the area as it heals.
- LIPOGEMS is the only FDA-cleared device that gently micro-fragments the patient's adipose tissue to achieve a minimally manipulated human cell and tissue product that preserves the cell and tissue microarchitecture of the original tissue.
- Minimal manipulation: For structural tissue, minimal manipulation means that the processing of the tissue does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.
- You can describe where the device can be used:
 - LIPOGEMS can be used as an alternative for in-office applications or as an adjunct to surgery in an outpatient surgical setting (example: orthopaedic surgery or arthroscopy).
 - The device is intended for use in the following specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, and other surgical disciplines.
 - LIPOGEMS is intended for homologous use, which means that the tissue is performing the same basic function (or functions) in the recipient as in the donor (recipient and donor are the same in this case)
- You can state the indications:
 - The Lipogems System is a sterile medical device intended for the closed-loop processing of autologous (your own) fat tissue in medical procedures involving the harvesting, concentrating and transferring of a patient's own fat (adipose) tissue harvested with a legally marketed lipoplasty system. This can be used as an alternative, and/or adjunct to surgery, to support a repair and may promote healing in orthopaedic and arthroscopic surgery. Lipogems may or may not be appropriate for all patients.
- You can describe the features and benefits:
 - **Compliance:** Only FDA-cleared method that gently micro-fragments the adipose tissue while preserving the cell and tissue micro-architecture
 - **Convenience:** Disposable, closed-loop system processing kit containing all necessary harvesting tools that is convenient for a clinic or surgical setting
 - Single-use kit can be used to process plentiful volume of tissue for multiple treatment sites
 - **Easily Injected and Stays Where It is Put:** Result is a flowable, structural tissue that can be injected through a small gauge needle that tends to stay where it's put and acts as a natural structural tissue
 - **Total procedure time:** < 1 hour from prep to injection (less in conjunction with arthroscopy)
 - **Minimally invasive:** Through a small incision in the skin (typically abdomen or "love handles"), a 17 gauge blunt infiltration cannula is used to anesthetize subcutaneous fat tissue with a dilute saline/lidocaine/epinephrine solution (local anesthesia) and a 13 gauge blunt aspiration cannula is used to collect the adipose tissue with a vacuum syringe
 - **Wash and Rinse:** Closed-loop system uses only normal saline
 - Mild, mechanical forces are exerted on the tissue in saline (reduces the traumatic action on the tissue)
 - Washes and removes inflammatory impurities (oil and bloody residues)
 - **Resize:** Micro-fragments and reduces the size of tissue using a specialized resizing process
 - Preserves cell and tissue micro-architecture
 - Smaller, micro-fragmented size = increased surface area and interaction with treatment site
 - Minimal manipulation and handling of the tissue (enzyme-free processing)
- You can state the contraindications:
 - Lipogems is contraindicated for intravenous use and one should avoid any possible risk of intravenous injection by aspirating prior to injection and using a blunt injection needle in areas of vascularity.
 - Patient has an allergy to lidocaine
 - Patient is currently breastfeeding or plans to begin breastfeeding in the near future



- Other contraindications include the presence of any disease processes that may adversely affect wound healing and of poor overall health status of the individual. Examples include:
 - Current systemic infection
 - Hematologic abnormalities
 - Autoimmune disease
 - Currently prescribed blood thinners or anti-coagulant medications (check with PCP prior)
 - Undergoing treatment for a malignancy or blood borne disease
 - Has had a cortisone injection in the treatment site within 3 months prior.
- You can state the risk:
 - Individual results vary. Not all patients will have the same post-procedure recovery and activity level. See your physician to discuss your potential benefits and risks.
 - Like any medical procedure, there is a risk for soreness, redness, swelling, and/or pain. These procedures require needle access (size, location and depth vary depending on the procedure) and this may result in (but not limited to), discomfort, pain, apprehension, bruising, tenderness, bleeding, swelling, or infiltration at the injection site. Other symptoms that may occur include lightheadedness, fainting, nausea, or vomiting. There is slight risk of infection at the injection site and have minimal risk of adverse reactions or complications as with any other injection procedure. Since the fat is from your own body there is little concern of disease transmission, allergic reaction or tissue rejection. For patients with chronic medical conditions such as autoimmune, diabetes, heart or lung disease, circulatory diseases or obesity, extreme caution may be necessary.
 - There are rare but possible risks and complications due to fat transfer including an allergic reaction to the local anesthetic, damage to underlying structures, hematoma or seroma (an accumulation of blood or fluid under the skin that may require removal), changes in sensation, unsatisfactory results that may necessitate additional procedures, permanent discoloration caused by a ruptured blood vessel at the treatment site, calcification, a divot in the area of the tissue harvest, peri-operative bleeding, a blood clot at the treatment or donor site, an infection, scar tissue, and a fat embolism caused by a fat injection mistakenly directed into a blood vessel, and death.
- You can state relevant statistics/facts:
 - Cases: Approx. 8,000+ cases performed worldwide in a variety of clinical indications
 - Award: Best New Technology in Sports Medicine in 2016 ---awarded upon the recommendation of sports medicine physicians from leading institutions across the United States
 - Research:
 - Partnered with leading researchers and institutions to validate and provide high quality evidence
 - Over 20 clinical studies using Lipogems in various clinical indications are being performed worldwide
- You can have testimonials
 - You can state general clinical outcomes but not specific outcomes. (For example, “I (or my patients) can now walk again” would NOT be allowed as it implies a curative result).
 - You can describe emotions (example: I am so happy)
 - You can state why you offer Lipogems (example: I consider Lipogems to support patients repair and healing in the joint space or I offer Lipogems for patients that want to improve mobility or candidates for joint replacement surgery)

Important Notes:

- Suggested to use qualifiers (example: may, could, potentially)
- Do not make any guarantees (example: it will, you should be able to)



“Best practice” calls for conservative language around topics that the FDA might consider too aggressive with regard to claims or marketing efforts, therefore:

- Do not claim that the use of Lipogems is to specifically treat or cure osteoarthritis, osteochondritis dissecans, or any specific pathology by diagnosis or CPT code. Instead you can state that this may be an alternative option for patients that do not qualify or wish to have surgery yet.
- Do not claim that Lipogems is an absolute alternative to a surgical repair (i.e., ACL, rotator cuff, etc).
- Do not directly attribute the benefit of Lipogems to Stem Cells, Stromal Cells, or Mesenchymal Stem Cells. Instead you can describe what adipose tissue is and that it contains a variety of cells, including vascular cells, progenitor cells, and regenerative or naturally reparative cells. You can describe what Lipogems does (see above)
- Do not claim or state that Lipogems selectively isolates or purifies any specific cell type.
- Do not say the product is intended for use as a liposuction device. Instead please state that Lipogems is designed and intended as an adipose tissue harvesting device for fat transfer.
- Do not state or claim that Lipogems will relieve pain or cure arthritis.
- Do not mix Lipogems with other agents (PRP, bone marrow, HA, cortisone).

If you have any questions on compliance, please email info@lipogems.us.com